

# EXHIBIT P

## REVIEW ARTICLE

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## Waveguide-enhanced mid-infrared chem/bio sensors

Boris Mizaikoff

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Despite providing the opportunity for directly sensing molecular constituents with inherent fingerprint specificity in the 2.5–20  $\mu\text{m}$  spectral regime, mid-infrared optical sensing technologies have not yet achieved the same penetration in waveguide-based chem/bio sensing compared to related sensing schemes operating at visible and near-infrared frequencies. In this review, current advances in mid-infrared chem/bio sensor technology will be highlighted and contrasted with the prevalent bottlenecks that have to date limited a more widespread adoption of mid-infrared sensing devices. However, with the increasing availability of advanced light sources such as quantum cascade lasers and the advent of on-chip semiconductor waveguide technologies, a prosperous future of this sensing concept for label-free detection in environmental analysis, process monitoring, and bioanalytics is perceived.

## 1. Introduction

The mid-infrared (MIR) spectral range extending from 2.5 to 20  $\mu\text{m}$  is known for providing highly discriminatory information due to the excitation of inherently specific fundamental vibrational and vibro-rotational transitions that are characteristic of molecular species in the liquid phase and in the vapor phase. In particular, organic molecules may be characterized *via* their fingerprint spectra, thus rendering infrared spectroscopy among the classical analysis techniques for identifying and structurally characterizing molecular species. With the advent of MIR transparent fiberoptic waveguide materials in the late 1980s, the comparatively young history of MIR fiberoptic chem/bio sensors has been initiated taking advantage of materials including heavy metal fluorides, chalcogenide glasses, polycrystalline silver halides (AgX), tellurium halides (TeX), single-crystalline sapphire, and hollow waveguide (HWG) structures.<sup>1</sup> Comparable to the evolution of fiberoptic chem/bio sensing technology in the visible (VIS) and near-infrared (NIR) spectral range, a diverse field of applications in environmental analysis, process monitoring/control, safety/security/surveillance, and the clinical/biomedical field was also anticipated for the MIR regime.<sup>2</sup> Since last reviewing MIR fiberoptic sensors a decade ago,<sup>3</sup> and despite the continuous evolution and increased availability of mid-infrared light sources, waveguide technology, and detection devices chem/bio sensors in the 2.5–20  $\mu\text{m}$  spectral window have not yet seen the breadth of applications in the analytical sciences that has been observed for optical sensing schemes in adjacent spectral ranges. Evidently, the fundamental

sensor technology is to date not as mature compared to other frequency ranges, thus rendering MIR chem/bio sensors still a rather unconventional option in optical sensing.

Hence, prior to reviewing the current state-of-the art and recent advances in waveguide-based MIR chem/bio devices, we should briefly discuss the reasons for MIR technology lagging behind VIS/NIR optoelectronics, and even ask the provocative question ‘Do we need to advance into the MIR spectral regime given the maturity of optoelectronics and photonics in the VIS and NIR?’

## 2. Why mid-infrared is different. . .

Waveguide-based – and in particular fiberoptic – sensing schemes have matured in recent decades around the development of optical communication technologies. With a distinct wavelength of 1.55  $\mu\text{m}$  set as the standard frequency for optical telecommunications, the corresponding light sources (*e.g.*, semiconductor laser diodes), waveguides (*e.g.*, silica, quartz, and polymer fibers), and detectors (*e.g.*, Si photodiodes) have rapidly evolved to performance levels close to or at their theoretical limits at coincidentally decreasing costs. NIR (800–2500 nm) spectroscopy and sensing technologies have tremendously benefited from this development *via* optoelectronic components directly derived from these technologies. Despite spectrally significantly broader molecular overtone vibrations, chemical analysis based on NIR spectroscopic techniques has become ubiquitous. Likewise, on-chip NIR sensing schemes nowadays utilize advanced integrated optics concepts such as ring resonators initially developed as on-chip telecommunication components (*e.g.*, for wavelength-division multiplexing).<sup>4</sup>

Given the distinct and spectrally much narrower vibrational/rotational features distributed over a much broader wavelength

*Institute of Analytical and Bioanalytical Chemistry, University of Ulm,  
Albert-Einstein-Allee 11, 89081 Ulm, Germany. E-mail: boris.mizaikoff@uni-ulm.de;  
Web: http://uni-ulm.de/iabc; Fax: +49 731 50-22763; Tel: +49 731 50-22750*

region in the MIR regime, it is immediately evident that molecule-specific analytics in the 2.5–20  $\mu\text{m}$  band requires a wide variety of optical components and materials; or, in other words – the ‘telecom model’ simply does not apply. While a few optical materials are sufficient to bridge a comparatively narrow spectral band as in the NIR, a range of materials covering a significantly larger spectral window is required for optoelectronic devices operating in the MIR, which affects all crucial sensor components: the light source, waveguide, and detector. In addition, most commonly applied optical materials (*e.g.*, waveguides) in the VIS and NIR are opaque at MIR frequencies, and the bandgap of Si as the currently dominating semiconductor material (*e.g.*, detectors) in the NIR is of limited use. Given this required diversity in materials, properties, and components, the costs per device remain significantly higher in comparison to the NIR.

For a short period of time during the last decade, it was on the horizon that MIR (opto)material science may receive a similarly dynamic boost, as short-range telecommunication was considered advantageous in the MIR and THz spectral band. Albeit the apparent lack of – at least compared to the NIR – cheap light sources and detectors, and limitations due to the available atmospheric windows, it was anticipated that the concepts for data transfer at short ranges may rapidly advance long-wavelength optoelectronic technology. However, with (organic) light emitting diode ((O)LED) technology developing at such an incredible pace, it is proposed that short-range optical communications rather progress towards the VIS regime based on the ubiquitous and nowadays even mandated prevalence of LED light sources, which may simultaneously serve as optical communication transmitters and hubs, if appropriately modulated.<sup>5</sup> Clearly, sensing technologies operating in the visible spectral regime directly benefit from these developments, similar to NIR sensing during the first telecommunications revolution.

Hence – where does that leave MIR optical technologies? Evidently, technological advancements may in contrast be problem-driven by the demands and challenges inherent to molecular specific analysis and sensing, rather than telecommunications. While it should be noted here that of course military and security applications in the areas of countermeasures (*i.e.*, MIR laser technology) and imaging (*i.e.*, focal plane mercury–cadmium–telluride (MCT) arrays) are the main driving forces, label-free chem/bio sensing – an inherent advantage and unique to molecular spectroscopy – may fertilize developments in waveguide technology and system miniaturization even toward on-chip MIR devices. In the latter case and with particular focus on potential microfabrication of waveguides, optical structures and surfaces, *etc.* fabrication tolerances are significantly higher at longer wavelengths, *i.e.*, defect size, surface roughness, feature dimensions, and feature distances are on the order of magnitude of a couple of 100 nm. In principle, manufacturing and (micro)fabrication should be easier, less costly, and with higher yield for integrated optical components and photonics at MIR wavelengths.

Hence, despite this distinctly different evolution and less mature technology base compared to conventional optical sensing technologies, if we ask again the question ‘Do we need

to advance into the MIR spectral regime given the maturity of optoelectronics and photonics in the VIS and NIR?’, the answer is clearly – yes:

- (i) No other spectral range offers the level of molecular selectivity that is inherent to the MIR window.
- (ii) Narrow and sharp spectral features enable discrimination and quantification of multiple constituents even in complex mixtures and matrices.
- (iii) There is significant potential for label-free (bio)diagnostics based on molecular fingerprints.
- (iv) (Micro)fabrication tolerances increase with increasing wavelength when adopting semiconductor/on-chip technologies.
- (v) Multivariate calibration, data evaluation, and classification methods (*i.e.*, chemometrics) provide enhanced performance with more pronounced spectral features.

In conclusion, if the main technological bottlenecks discussed above can be adequately addressed, clearly a more widespread adoption of the 3–20  $\mu\text{m}$  spectral window in chem/bio sensing is not only envisaged, but indeed ensured.

### 3. Waveguide-enhanced diagnostics

Conventionally, this critical review would have been called ‘fiber-optic mid-infrared chem/bio sensors’ – why ‘waveguide-enhanced’? A wide variety of optical (chem/bio) sensors use optical fibers or other waveguides (*e.g.*, planar structures, hollow waveguides, *etc.*) for propagating photons from a light source to a measurement location, and after interaction with the sample/analyte to an optical detector.<sup>6</sup> Yet, this review is focused on sensing schemes that take ‘functional advantage’ of waveguides as an active transducer, rather than merely serving as a light conduit. From an analytical perspective, this is an essential function, as the transducer is the vital component of an optical sensor ensuring reproducible interaction between photons and molecules for producing an analytical signal with appropriate precision and accuracy.

Currently and with only few exceptions, absorption phenomena are utilized as the signal-generating optical mechanism in MIR sensing. The waveguide may in addition enhance the generated optical signal, as discussed below.

In contrast to chem/bio sensing schemes based *e.g.*, on the excitation of fluorescence or Raman scattering, optical absorption techniques lack a distinct variable for analytical signal enhancement, *i.e.*, the intensity of the light source. While increasing the power of the light source directly and positively affects the scattering probability in Raman sensing and the fluorescence quantum yield, following the Beer–Lambert law (*i.e.*, the absorbance  $A = \epsilon cl = \log(I_0/I)$  with  $I_0$  as the light intensity before interaction with the sample, and  $I$  after interaction,  $\epsilon$  as the molar absorption coefficient, and  $c$  as the analyte concentration) it is evident that the absorption is independent of the intensity of the light source. Consequently, for increasing the sensitivity of absorption-based optical sensors, we have to focus on amplifying the analytical signal *vs.* the background noise level, *i.e.*, maximizing the signal-to-noise ratio (SNR).

In essence, we have two complementary options to achieve this: (i) chem/bio amplification, and (ii) optical amplification.

Chem/bio amplification entails modifying the waveguide surface with chemical or biological molecular recognition and enhancement schemes. For example, the target constituents are attracted *via* a bioreceptor such as an enzyme or antibody or a biomimetic receptor such as an aptamer or imprinted polymer to the waveguide surface. Alternatively, they may be enriched/preconcentrated – usually *via* a polymer, sol-gel, or hydrogel membrane – within the analytically probed volume, which constitutes the classic concept of chemical sensors and biosensors, respectively.

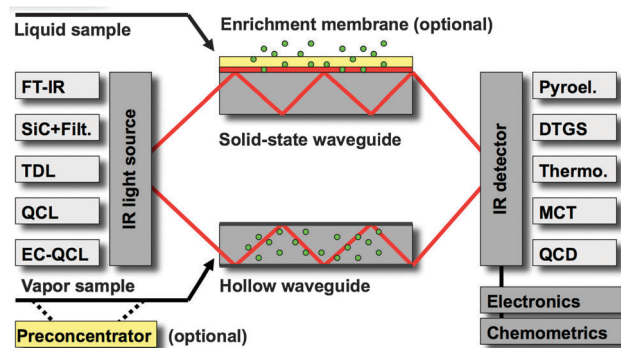
Optical amplification comprises a variety of strategies for improving the SNR such as *e.g.* focusing radiation using free-space optics or taking advantage of near-field effects. Being less suitable for – ideally portable – optical sensing devices, confining photons within a waveguide enables efficient propagation of radiation to an active transduction region of the same or a different waveguide structure, thereby ensuring that a maximum of photons interacts with the molecules of interest in a potentially small analytical volume. On top of that, resonating structures such as ring-, race-track-, or disc-resonators as well as free-space optical cavities enable the photons to interact multiple times with the constituents of interest, thereby giving rise to enhanced optical signals with a further improved SNR.

Hence, by smartly designing the waveguide and the waveguide geometry (*e.g.*, tapered fibers, resonating structures, *etc.*) one may optically enhance the signal, thereby leading to an increased SNR, which in turn benefits the detection of reduced analyte concentrations. Of course, both signal amplification strategies are mutually complementary and may be jointly utilized within one sensing scheme. Consequently, rather than only focusing on conventional fiberoptic sensors, any kind of waveguide is considered herein, with particular emphasis on structures that assist in optically enhancing the generated analytical signal, *i.e.*, waveguide-enhanced diagnostics, which has been the most significant advancement toward increasing the sensitivity in MIR sensor technology in the past decade.

## 4. Emerging technologies

The main optical components of waveguide-based sensor systems are (i) the light source, (ii) the waveguide/transducer, and (iii) the detector (Fig. 1). Due to the fact that conventional MIR spectrometers such as Fourier transform (FT-IR) instruments essentially utilize the same detector technology applied in waveguide-based IR sensor systems ranging from sophisticated semiconductor devices (*e.g.*, mercury-cadmium-telluride (MCT), indium-antimonide (InSb), *etc.*) to comparatively simple pyroelectric detectors and thermopiles, a discussion of recent advances is omitted here. It should be noted though that most recently and in analogy to quantum heterostructures serving as MIR laser light sources first quantum cascade detectors (QCD) have been demonstrated, which may in future facilitate the integration of highly miniaturized detector technology.<sup>7,8</sup>

The major breakthrough in MIR sensor technology during recent decades has certainly been the introduction of the quantum



**Fig. 1** Overview of the most prevalent waveguide-enhanced MIR sensing principles. FT-IR – Fourier transform infrared spectrometer; SiC + Filt. – silicon carbide filament IR emitter with filters for spectral region selection; TDL – tunable (lead salt) diode lasers; QCL – quantum cascade laser; EC-QCL – external cavity coupled QCL; Pyroel. – pyroelectric detector (room temp. operation); DTGS – deuterated triglycine sulfate detector (room temp. operation); Thermo. – thermopile detector (room temp. operation or thermoelectrically cooled); MCT – mercury-cadmium-telluride semiconductor detector (room temp. operation up to liquid nitrogen cooled); QCD – quantum cascade detector (room temp. operation). For chem/bio sensing, liquid phase sensing schemes may entail appropriate waveguide surface modification. In vapor phase sensing, enrichment/preconcentration is usually performed off-line *via* trapping at appropriate sorbent materials and subsequent thermal desorption into a small and defined gas volume.

cascade laser (QCL). While QCLs already celebrate their 20th anniversary of ‘experimental demonstration’ in 2014,<sup>9</sup> a comprehensive discussion is provided herein, as their development is among the major driving forces in advanced IR sensor technology.

Likewise, the recent emergence of semiconductor on-chip waveguides paves the way toward fully integrated MIR photonic systems rendering ‘IR-lab-on-a-chip’ a conceivable concept. Last but not least, substrate-integrated hollow waveguides promise a new level of integration for vapor phase MIR sensor technology.

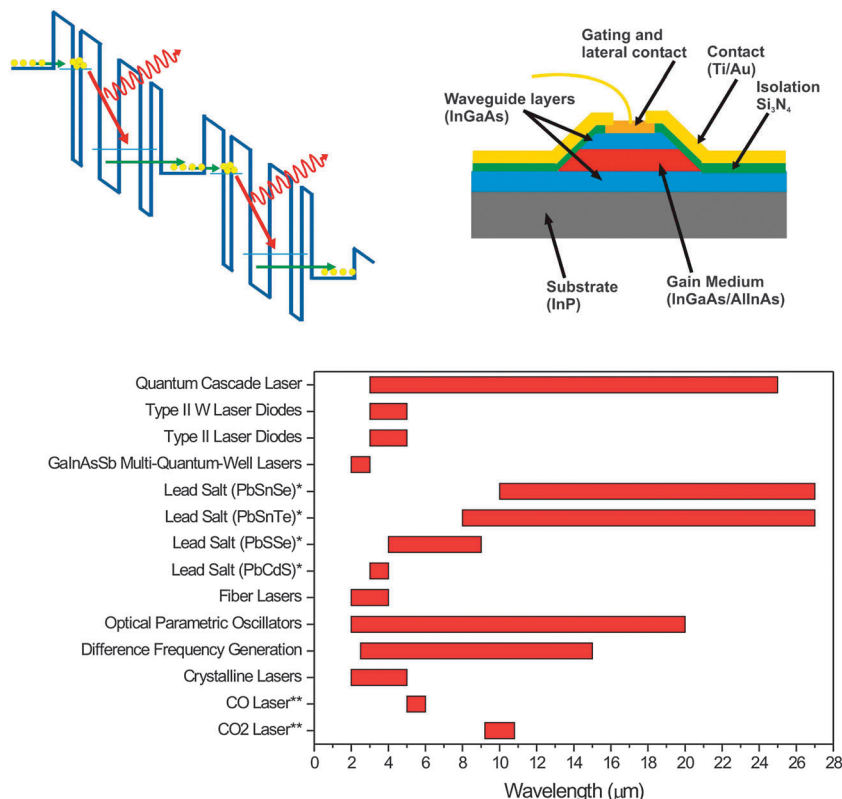
In contrast to MIR detector technology, these critical components are of specific use in waveguide-based sensors with little applicability in conventional IR spectroscopy.

### 4.1 Quantum cascade lasers

While conventional narrow bandgap semiconductor laser diodes made from *e.g.*, lead salt materials or IV–VI compound semiconductors generate photons by radiative recombination of electrons from the conduction band, and holes from the valence band, QCLs take advantage of repeating intersubbands within the conduction band, which are tailored by designing appropriate quantum well heterostructures.<sup>10</sup> As schematically shown in Fig. 2, electrons introduced to the upper intersubband relax into the lower intersubband generating MIR photons with an energy corresponding to the energy difference between these bands. Since QCLs provide a cascade (typically up to 40) of such active regions, each electron may generate several photons. Of particular importance is the fact that using one material system, laser diodes emitting throughout the entire MIR band may be designed.

Some of the main disadvantages of conventional narrow band gap semiconductor lasers have recently been resolved by QCLs.





**Fig. 2** (top left) Simplified scheme of a quantum heterostructure under bias with its electronic transitions. Electrons enter the heterostructure *via* an injector region (left of the heterostructure) and relax into a lower energy state (red arrow) releasing a photon. Population inversion is achieved, if the electron is rapidly ejected from that quantum well *via* a longitudinal-optic (LO) phonon transition (green arrow), and may enter the next injector region. This process is repeated for each active structure (typically up to 40 periods), thereby providing a cascade effect, *i.e.*, a single electron may produce multiple photons. (top right) In the schematic QCL structure electrons are injected *via* the wire bonds shown on the lateral contact layer, and then tunnel through the gain medium. Photon generation occurs in the gain medium layer with photon emission toward the reader. (bottom) Lasers and laser-based light sources emitting in the MIR widely vary in their power output, tunability, and spectral coverage. QCLs are the only MIR laser source that may cover the entire MIR spectrum based on a single material system.

Meanwhile, a wide variety of studies have demonstrated superior sensitivity and selectivity in gas sensing applications using QCL light sources in combination with various types of gas cells and different laser tuning ranges.

Using appropriate emission wavelength tuning strategies, such laser diodes potentially serve as miniaturized spectrometers. Conventional tuning of the lasing wavelength *via* temperature or injected current yield limited tuning ranges (*i.e.*, few wavenumbers). Advanced strategies therefore utilize arrays of fixed wavelength QCLs each providing a different lasing wavelength,<sup>11,12</sup> or couple the laser diode to an external cavity (EC-QCL), whereby an angle-scanned grating provides wavelength-selective feedback.<sup>13,14</sup>

While QCLs remain significantly more expensive compared to corresponding light sources in the VIS and NIR, it is anticipated that their increased adoption for military applications and in MIR sensor technology will reduce costs to a competitive level.

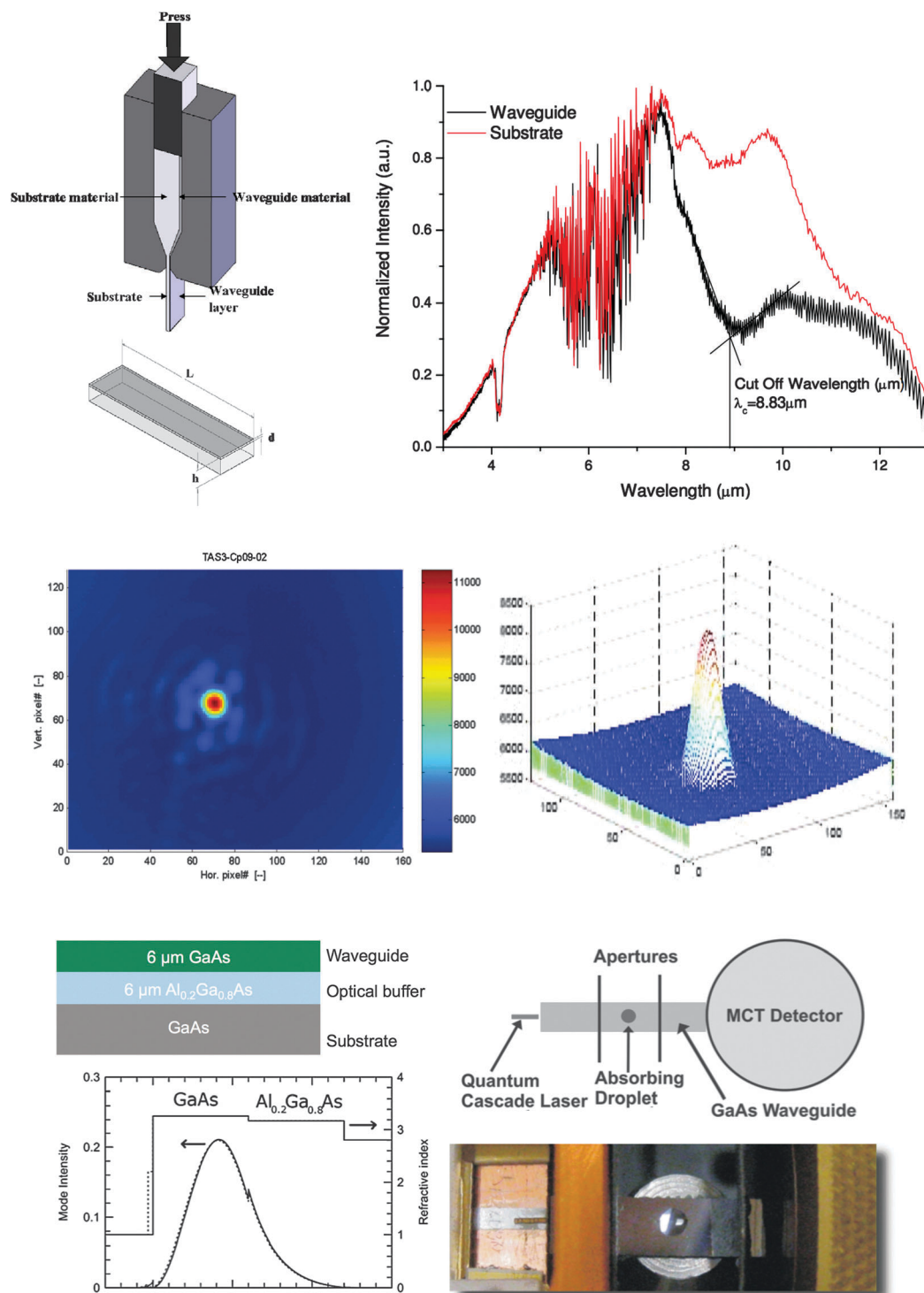
#### 4.2 Semiconductor on-chip waveguides

Despite the evident progress in light source technology, complementary waveguide structures maintaining the advantageous properties of the emitted laser radiation (*i.e.*, single-mode waveguides) have only very recently been introduced (Fig. 3).

Among the variety of MIR transmitting waveguide materials polycrystalline silver halides, and amorphous chalcogenide glasses are the most prevalent ones with only few recent reports demonstrating waveguides facilitating single-mode behavior.<sup>15,16</sup>

The group of Mizaikoff and collaborators has pioneered the first entirely semiconductor-based thin-film IR waveguides made from GaAs/AlGaAs, which were epitaxially grown as a 6/6 μm layer across an entire wafer substrate *via* molecular beam epitaxy (MBE) or using metal-organic vapor-phase epitaxy (MOVPE).<sup>17</sup> Hence, for the first time the useful spectral window for on-chip MIR waveguides has been extended to 13 μm providing a sound basis for chip-integrated MIR sensor technology and complex MIR photonic structures taking advantage of mature micro-fabrication techniques for GaAs.

First GaAs/AlGaAs thin-film IR waveguides were grown *via* MBE on a Si-doped GaAs wafer substrate with a refractive index of  $n = 2.8$ . A 6 μm  $\text{Al}_{0.2}\text{Ga}_{0.8}\text{As}$  optical buffer layer ( $n = 3.2$ ) was epitaxially deposited followed by a 6 μm GaAs waveguide core ( $n = 3.3$ ). The obtained mode profile along the  $x$ -axis was single-mode. After cleaving the wafer into waveguide slabs, TM polarized light emitted by a DFB QCL at a wavelength of  $974\text{ cm}^{-1}$  was directly coupled into the GaAs core layer and detected at the distal end of the waveguide using a MCT detector. With this system,



**Fig. 3** (top left) Extrusion of a planar silver-halide waveguide with a layer thickness  $d = 43 \mu\text{m} \pm 2 \mu\text{m}$ . (top right) Normalized FT-IR spectra obtained through the substrate vs. the planar silver-halide waveguide. A drop in intensity is clearly evident around  $9 \mu\text{m}$ , which is the cut-off wavelength for a non-polarized measurement. (middle) Far-field intensity distribution at  $10.6 \mu\text{m}$  measured at a distance of approx. 10 mm from a 36 cm long single-mode Ga-coated chalcogenide fiber prepared by the rod-in-tube vacuum method. (bottom left) Thin-film single-mode GaAs/AlGaAs waveguide structure with computed optical mode profile (right axis: refractive index profile; left axis: optical mode profile). (bottom right) Single wavelength emitting QCL coupled to GaAs waveguide slab. Experimental setup for QCL-based evanescent field absorption measurements with the QCL pigtail coupled to a GaAs waveguide and a droplet of absorbing analyte at the waveguide surface. Reproduced and adapted with permission from ref. 15–17.

the detection of  $0.5 \mu\text{L}$  droplets of acetic anhydride at the waveguide surface *via* evanescent field absorption was demonstrated.

These pioneering measurements have established the first generation of MIR semiconductor thin-film waveguide structures based

on GaAs/AlGaAs initializing the development of on-chip MIR chem/bio sensing devices.

#### 4.3 Substrate-integrated hollow waveguides

Hollow waveguides (HWGs) are essentially hollow-core light-pipes initially designed for high-power surgical laser applications,<sup>18</sup> and have only recently attracted interest for MIR sensing applications (Fig. 4).<sup>19</sup> Conventional HWGs comprise a structural tube (*e.g.*, silica) coated on the inside hollow core wall with a metal (*e.g.*, Ag), and a protective dielectric (*e.g.*, AgI). Thus, MIR radiation propagates *via* reflection along the inside walls. Advantageously for sensing applications, they may simultaneously serve as a optically highly efficient miniaturized IR absorption cell for vapor analysis. The hollow core with typical diameters in the range of 2000–200  $\mu\text{m}$  encloses a minute gas volume (few hundreds of  $\mu\text{L}$ ), while simultaneously establishing a well-defined absorption path length. As discussed later, this optical efficiency leads to comparable or even enhanced sensitivity *vs.* conventional multi-pass gas cell configurations. Given the small volume of probed gas, and the resulting short sample transition times, this configuration provides significant benefits over conventional multi-pass gas cells.

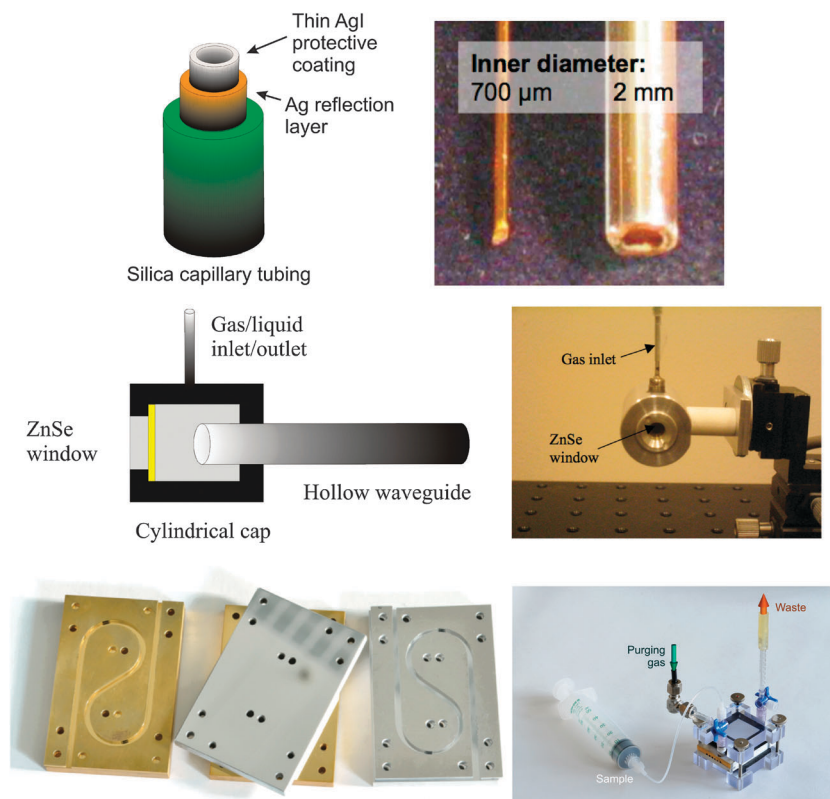
However, integration of HWGs into compact sensing devices is limited due to the length and mechanical flexibility of the fiberoptic HWGs resulting in a large system operational footprint, if extended absorption path lengths are required.

Furthermore, mechanical motion or vibrations of the waveguide affect quantitative measurements. While coiling of the waveguide for reducing the footprint is conceivable, substantial signal attenuation losses due to bending, and mechanical stresses imposed onto the internal coatings limit the utility of this approach.

Consequently, Mizaikoff and collaborators have developed a new generation of HWG structures termed substrate-integrated hollow waveguides (iHWGs) based on a meandering hollow waveguide channel structure for vapor phase sensing applications.<sup>20</sup> With the waveguide embedded into a solid-state, planar substrate material combination with any MIR light source (*e.g.*, QCL, SiC filament, FTIR, *etc.*) is facilitated. Now maintaining a possibly compact device footprint (Fig. 4) renders this concept ideally suited for vapor phase sensing *e.g.*, in exhaled breath diagnostics.<sup>21</sup>

## 5. Fundamental sensing principles

As discussed above, with few exceptions, absorption-based MIR sensors currently dominate the field taking advantage of the waveguide serving as an active optical transducer: (i) evanescent field absorption for liquid phase sensing, and (ii) absorption inside a hollow waveguide structure for vapor phase sensing. First concepts toward surface plasmon resonance sensors in the MIR have recently emerged, and will be briefly outlined.



**Fig. 4** (top) Structure of a conventional silica hollow core waveguide along with coupling cells for simultaneously serving as a miniaturized gas cell and propagating MIR photons. (bottom) Substrate-integrated hollow waveguide structure (iHWG) based on Al substrates with cover plates (one substrate has been additionally modified with an Au reflective layer) along with an assembled device for breath gas sensing.

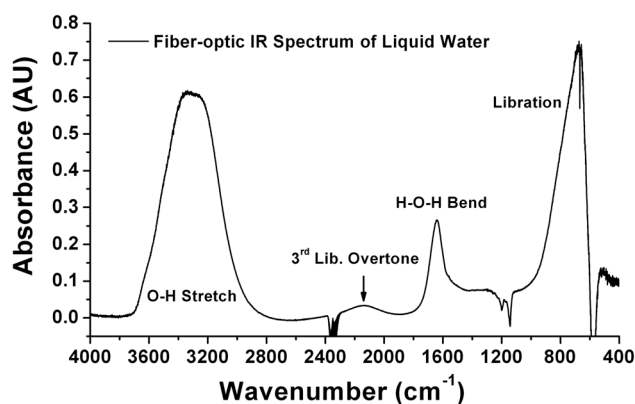
### 5.1 Evanescent field absorption

While fundamentally most optical sensing techniques known throughout the more common frequency ranges from the VIS to the NIR may in principle be translated into the MIR frequency regime, practically relevant liquid phase IR sensing suffers from a major limitation – the absorbance characteristics of water (Fig. 5). Hence, only few unobstructed spectral windows provide access to the spectral fingerprints of *e.g.*, dissolved organic molecules. In conventional transmission-absorption IR spectroscopy, this problem is significantly reduced by using thin-film transmission cells, which ensure a liquid layer thickness of usually 20–300  $\mu\text{m}$ . Thereby, the absorption of the aqueous background matrix is limited. This concept has successfully been used for coupling a tuneable EC-QCL to a thin-film transmission-absorption experiment for detecting glucose, lactate, and triglycerides in blood serum.<sup>22</sup> However, such thin film cells are prone to clogging, especially if real-world samples with complex matrices are analyzed. Thus, they are considered less suited for sensing applications. Hence, evanescent field spectroscopy has emerged as the dominating optical sensing principle for liquid phase IR sensing especially within aqueous matrices, as the sampled volume is defined by the penetration depth ( $d_p$ ) of the evanescent field, which is only a few micrometers at MIR frequencies.

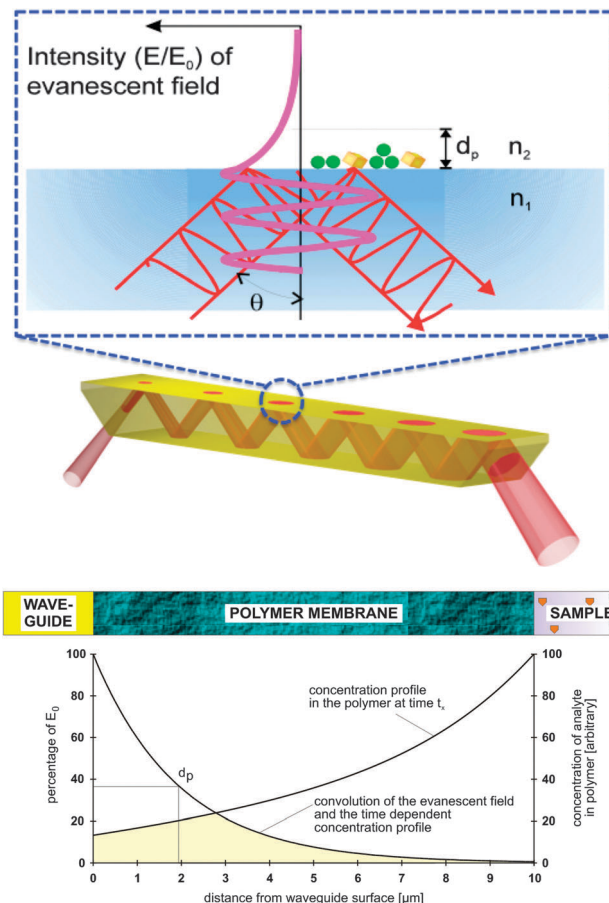
In brief, the penetration depth ( $d_p$ ) of the evanescent field is defined as

$$d_p = \frac{\lambda}{2\pi\sqrt{n_1^2 \sin^2 \theta - n_2^2}}$$

where  $\lambda$  is the wavelength of the incident radiation,  $n_1$  is the refractive index of the waveguide,  $n_2$  is the refractive index of the adjacent medium,  $\theta$  is the incidence angle of the photons at the waveguide/sample interface (Fig. 6). How can we now maximize the sensitivity in evanescent field absorption sensing?



**Fig. 5** Typical IR spectrum of liquid water collected *via* evanescent field absorption spectroscopy using a silver halide fiberoptic waveguide as the active transducer (approx. 10 cm of the fiber was immersed into aqueous solution) externally coupled to a FT-IR spectrometer. The four major absorption features of water are indicated (minor atmospheric CO<sub>2</sub> absorbance (approx. 2350  $\text{cm}^{-1}$ ) during recording under ambient conditions, and of polymer ferrules at approx. 1150  $\text{cm}^{-1}$ , which have been used to seal the fibers into the measurement cell). The detector cut-off occurs at  $\sim 680 \text{ cm}^{-1}$ . This spectrum is an average of 250 sample scans collected at 0.5  $\text{cm}^{-1}$  resolution (Lib. = libration).



**Fig. 6** (top) Schematic representation of evanescent field absorption spectroscopy. A trapezoidal internal reflection element (IRE) is exemplarily shown (modeled material for internal reflections: ZnSe), although photons propagate in a similar fashion along fiberoptic waveguides. Discrete internal reflections give rise to an evanescent wave, which emanates at the waveguide surface and exponentially decays into the adjacent medium, if the refractive index of the core-only waveguide  $n_1$  exceeds the refractive index of the adjacent medium  $n_2$ . Analytes present within the penetration depth  $d_p$  of the evanescent field may absorb radiation, and therefore attenuate the field at the resonance frequencies of the molecular vibrations, *i.e.*, attenuated total reflection spectroscopy and sensing. In contrast to VIS and NIR sensing, the evanescent field in the MIR typically penetrates several micrometers into the sample, thus forming a quasi thin-layer sample cell defined by  $d_p$  around the waveguide structure. Consequently, even highly opaque or strongly absorbing media such as *e.g.*, aqueous solutions may readily be probed. (bottom) If the surface of the waveguide is modified with a chem/bio sensing interface, *e.g.*, a polymer membrane enriching molecules, the obtained information is generated by the convolution of the time dependent concentration profile of the analyte diffusing into a chemical recognition layer, and the intensity profile of the evanescent field.

The critical angle  $\theta_c$  at which total internal reflection occurs is defined as

$$\theta_c = \arcsin \frac{n_2}{n_1}$$

The theoretical number of internal reflections ( $n$ ) in a waveguide may be calculated as

$$n = \frac{L}{a} = \frac{L}{d \tan \theta}$$

where  $L$  is the length of the active transducing (sensing) region of the waveguide,  $d$  is the waveguide thickness, and  $a$  is the



distance between each reflection. Thus, at the same sensing length  $L$  and at a given angle of incidence  $\theta$ , a decreasing waveguide thickness results in more internal reflections. Furthermore, the amplitude of the evanescent field  $E(x)$  decreases exponentially with increasing distance  $x$  from the waveguide surface following

$$E(x) = E_0 \exp\left(-\frac{x}{d_p}\right)$$

where  $E_0$  represents the intensity directly at the waveguide/sample interface. Thus, after  $n$  internal reflections within the waveguide, a total  $E_{\text{total}}(x)$  may be obtained (with  $x_1 = x_2 = \dots = x_n$ ) as

$$E_{\text{total}}(x) = \sum_{i=1}^n E_i(x_i) \approx nE(x) = nE_0 \exp\left(-\frac{x}{d_p}\right)$$

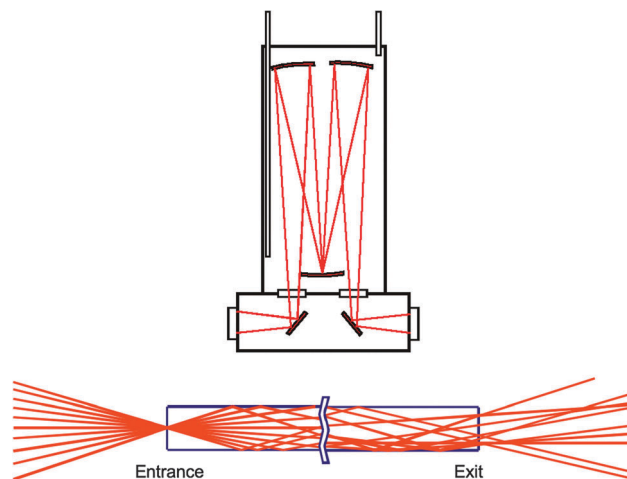
Therefore, the absorbance increases with  $n$ , *i.e.*, more internal reflections result in enhanced absorbance signals, which in turn provides the fundamental argument for the current trends in thin-film waveguide technology discussed in Section 4.

## 5.2 Absorption-based sensing in hollow waveguides

Vapor phase IR sensing is usually less affected by water, however, typically requires an extended absorption path length to ensure sufficient interaction between photons and molecules. Consequently, conventional gas phase IR spectroscopy takes advantage of so-called multi-pass gas cells (*e.g.*, White cell, Herriott cell, *etc.*), which utilize a series of mirrors folding the IR beam multiple times within a defined gas volume. While this strategy enables effective absorption path lengths of several tens of meters, the volume of such systems also ranges from a minimum of usually 200 mL up to several liters. Hence, the required sample gas volume, transient sample time, and bulkiness of such gas cell assemblies render them less suitable for sensing applications. As a viable alternative, hollow waveguides have emerged, which provide a distinctly higher efficiency briefly discussed herein (Fig. 7).

The optical efficiency of such a hollow optical structure used in vapor sensing may be defined as the ratio of the optical path length to the cell volume. In a multi-pass gas cell, the reflections produce a series of radiation cones between the objective and the field mirrors, *i.e.*, the IR beam does not pass through the entire cell volume. Exemplarily, for a 3 m multi-pass gas cell (Gemini Scientific, Buena Park, CA, USA) with a volume of 375 mL, the IR beam only occupies approx. 85% of that volume. Given that HWGs are non-imaging optical elements, even after a short propagation length nearly the entire void volume is occupied by IR photons, therefore ensuring possible intimate interaction between MIR radiation and vapor phase molecules within the entire available sample volume.

In turn, the response time of a vapor sensing system is dependent on the optical efficiency of the gas cell as described above, and the flow response time of the gas cell, *i.e.*, the transient time of a sample through the void volume. For sensing applications in process monitoring, security/surveillance, for studying rapid combustion processes, or in exhaled breath diagnostics



**Fig. 7** (top) Schematic of a simple multi-pass gas cell (four passes) conventionally used in vapor phase IR spectroscopy. The optical efficiency is defined as the ratio of the optical path length and the cell volume. Evidently, the IR beam does not pass through the entire volume of the gas cell. (bottom) Schematic of infrared radiation propagating through a hollow waveguide as derived from Monte-Carlo ray tracing simulations indicating that eventually a much larger fraction of volume is occupied by photons. Dimensions not to scale.

timely feedback is required, therefore rendering analysis systems with extended response times less suitable.

Using concentration decay curves, a comparison between a 3 m multi-pass gas cell and a conventional hollow waveguide based on a silica structural tube coated on the inside with Ag/AgI with a length of 55 cm and an inner diameter of 2 mm (both coupled to a FT-IR spectrometer) was performed.<sup>23</sup> The resulting optical efficiency of the HWG was 32 *vs.* 0.8 for the multi-pass gas cell with the response time being 1/10th of the response time obtained with the multi-pass gas cell. Furthermore, it could be demonstrated that the HWG provides up to 60% more sensitivity (per meter optical path) compared to the multi-pass gas cell. This is related to the superior optical efficiency maximizing the photon density within the vapor phase sample volume, thereby impressively demonstrating the advantage of HWG structures for chem/bio sensing.

## 5.3 Emerging concepts: MIR surface plasmon resonance

Surface plasmon resonance (SPR) is nowadays considered a well-established optical principle that finds widespread use in chem/bio sensing.<sup>24</sup> Most commonly, internal total reflection configurations are used for the excitation of surface plasmons,<sup>25</sup> along with an increasing number of fiberoptic SPR sensors.<sup>26</sup>

It is quite surprising though that the spectral range of operation for SPR-devices is currently limited to the VIS-NIR regime, even though the MIR would provide significant advantages in terms of molecular information. However, since the obtained vibrational modes are comparatively weak, electric field enhancement techniques based on noble metal nanostructures are frequently required,<sup>27</sup> which in turn suggests that utilizing the advantageous characteristics of SPR devices in the MIR may be a viable option.



In a seminal study, Chen has shown a MIR SPR sensor system that may be used in air or water.<sup>28</sup> Surface plasmons were excited *via* a periodic doping profile embedded into an intrinsic silicon film, whereby the optical constants were tailored by the doping concentration. Thus, the obtained dispersion curves between the doped silicon and the analyte medium were effectively tuned according to the SPR wavelength such that the presence of an analyte gives rise to a reflectance dip, as demonstrated *e.g.*, for ammonium sulfate in water (Fig. 8). However, the optical configuration of this system requires angular interrogation of the active structure, which is of limited utility in sensing, *e.g.*, for lab-on-a-chip devices. Nevertheless, the fundamental feasibility of MIR-SPR sensing has impressively been demonstrated.

A novel concept for SPR-MIR waveguide-based sensing has recently been theoretically introduced by Esteban *et al.* describing the potential for exciting surface plasmons in corrugated

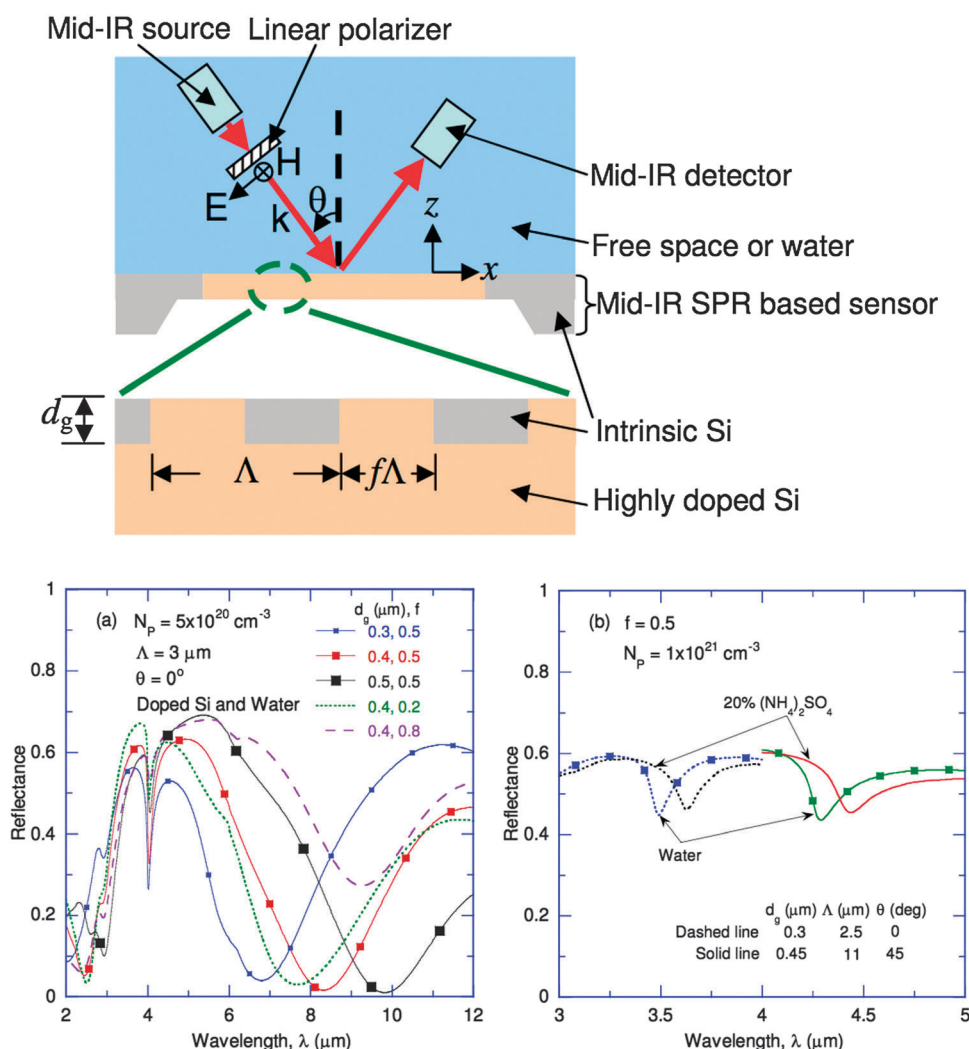
GaAs/AlGaAs thin-film waveguide structures, which is ideally compatible with on-chip integration strategies (Fig. 9).<sup>29</sup>

Herein, the phase-matching conditions between the effective refractive index of a noble metal (Au) coated semiconductor structure and the surface plasmon were calculated proposing a multi-layered device. The grating/corrugation period  $\Lambda$  is calculated following

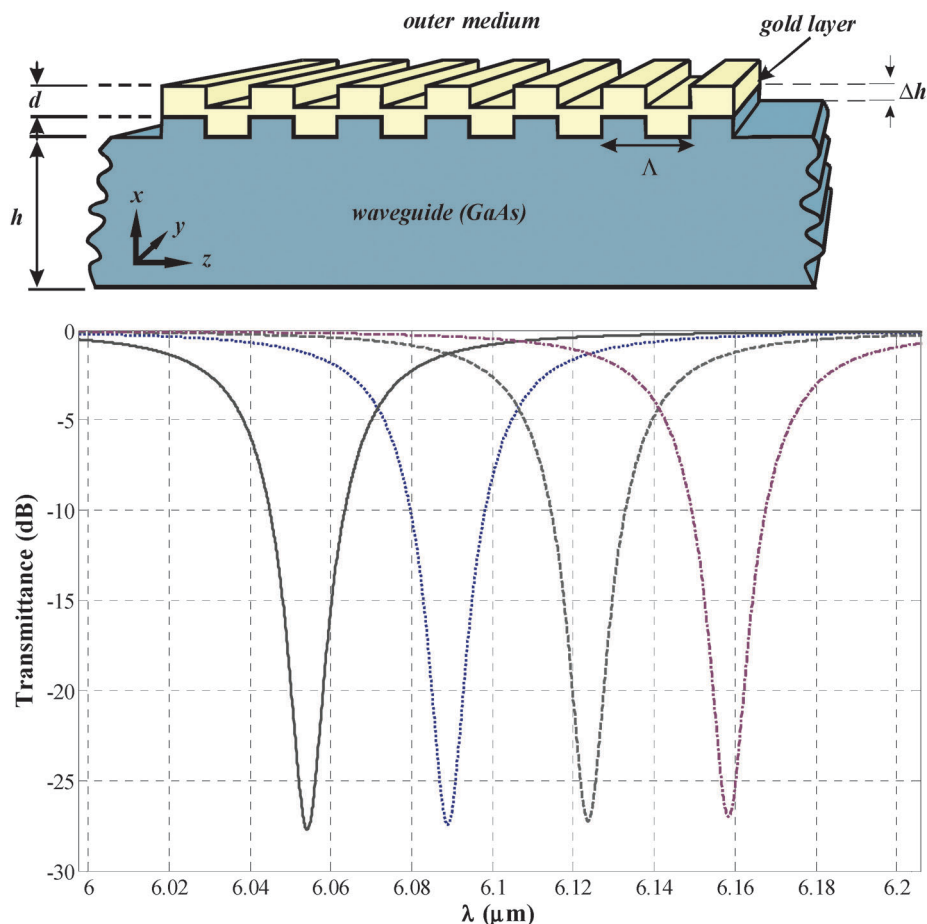
$$\Lambda = \frac{\lambda}{\text{Re}(n_{\text{eff,W}}) - \text{Re}(n_{\text{eff,SP}})}$$

where  $\lambda$  is the desired resonance wavelength,  $n_{\text{eff,W}}$  is the effective index of the fundamental TM mode for the waveguide, and  $n_{\text{eff,SP}}$  is the effective refractive index for the surface plasmon mode. A variation in the outer refractive index of the structure therefore translates into a change of the  $n_{\text{eff,SP}}$ .

Subsequently, the dispersion relations of the guided modes for the planar substrate, the metallic layer, and the outer (sample)



**Fig. 8** (top) Schematic of the optical setup for MIR SPR sensing in air or water based on a periodically doped silicon structure, as shown in the magnified cross-section of the sensor structure. (bottom left) Spectral reflectance spectra for MIR-SPR doped silicon sensors with different filling ratios ( $f = 0.2, 0.5$ , and  $0.8$ ) and intrinsic silicon thickness ( $d_g = 0.3, 0.4$ , and  $0.5 \mu\text{m}$ ). The sample medium is water with the surface plasmon excited at  $4 \mu\text{m}$  for all sensors. (bottom right) Detection of ammonium sulfate in water (binary mixture; 20% weight fraction  $(\text{NH}_4)_2\text{SO}_4$ ) at 298 K. Reproduced and adapted with permission from ref. 28.



**Fig. 9** (top) Schematic of a GaAs/AlGaAs waveguide-based MIR-SPR sensor comprising a corrugated GaAs waveguide with an Au layer. (bottom) Transmittance of the proposed device and expected shift. From left to right, the values of the outer refractive index are 1.57, 1.56, 1.55 and 1.54 respectively. The device has been calculated for a MIR wavelength of 6  $\mu\text{m}$ . Reproduced and adapted with permission from ref. 29.

medium were calculated. In contrast to previous study, the substrate itself serves as a waveguide, thereby avoiding external (angular) interrogation for excitation of the surface plasmons, thus facilitating full device integration for future MIR-SPR chem/bio sensing applications.

## 6. Applications of waveguide-based MIR chem/bio sensors

In the following, a representative selection of waveguide-based MIR sensing applications is discussed highlighting recently published measurement scenarios along with future trends in the field; a corresponding overview is provided in Table 1.

### 6.1 MIR chemosensors vs. MIR biosensors

While optical chemical sensors nowadays increasingly take advantage of MIR technologies, only few representative examples of biosensors have been published so far. This is mainly attributed to the fact that – with few recent exceptions – the sensitivity of waveguide-based IR liquid phase sensors remains insufficient for detecting small quantities of relevant biomolecules such as *e.g.*,

proteins or DNA. The fundamental feasibility of label-free evanescent field absorption detection of biomolecular interactions such as antibody–antigen interactions or ssDNA binding to a complementary strand has recently been demonstrated after immobilizing probe ssDNA at the surface of a ZnSe waveguide.<sup>30</sup> However, only if sufficient sensitivity is achieved using the strategies outlined in Section 4, label-free MIR bioassays may be envisaged.

Even enzymatic biosensing schemes combined with MIR transducers do not provide the same advantages generally known *e.g.*, for electrochemical biosensors. The rather complex molecular surface architectures required for the immobilization of biocatalysts usually gives rise to substantially cluttered background spectra in addition to spectral interferences by water, which results in limited spectral windows that are available for (bio)analyte detection.

Consequently, only if advanced waveguide-enhanced sensing and diagnostic concepts significantly improve the sensitivity while reducing the required sample amount, label-free MIR bioassays and MIR-lab-on-a-chip systems may be successful, as shown for first promising approaches discussed at the end of this section.

In contrast to biosensors, most chemosensors usually rely on a chemical recognition element, *i.e.*, a polymer membrane,

**Table 1** Summary of recent waveguide-based MIR chem/bio sensor applications

Waveguide material	Light source	Application	Analyte(s)	Ref.
Zinc selenide	FT-IR	Label-free mid-infrared DNA hybridization assay <i>via</i> surface-immobilized ssDNA	ssDNA	30
Calcium fluoride coupled to silver halide fibers	QCL	Hand-held safety/security sensing devices using fiber-coupled ATR prisms	Triacetone triperoxide (TATP)	31
Various MIR waveguides	FT-IR	Review on environmental sensing of water pollutants using polymer-coated MIR waveguides	Aromatic and halogenated hydrocarbons in general	32
Zinc selenide	FT-IR	Simultaneous sensing of aromatic hydrocarbons in water with polymer-coated waveguides	Benzene, toluene, <i>o</i> -, <i>m</i> -, <i>p</i> -xylene	33
Silver halide	QCL	Sensing of organic constituents at high concentrations with quantum cascade laser and cylindrical fibers	$\alpha$ -Tocophenol, acetone	34
Silver halide	QCL	Trace sensing of organic constituents with quantum cascade laser and planar tapered fibers	Acetic anhydride, urea	35
Silver halide	FT-IR	Silver halide fibers with surface-deposited grating couplers	Pesticides (diazinon, dichlorvos (DDVP), parathion)	36
Silver halide	QCL	Planar silver halide fibers with integrated FIB-fabricated grating couplers	Acetic acid	37
Ge-doped chalcogenide (GeSbSe)	FT-IR	Mid-infrared biosensor using antibody-decorated waveguide surfaces	<i>E. coli</i> O157:H7, <i>E. coli</i> K12, <i>S. enteritidis</i>	38
Zinc selenide	FT-IR	Quantitative determination of salt ions <i>via</i> their individual effects on the bulk water IR spectrum	$\text{Cl}^-$ , $\text{Na}^+$ , $\text{SO}_4^{2-}$ , $\text{Mg}^{2+}$ , $\text{Ca}^{2+}$ , $\text{K}^+$ , $\text{Br}^-$	39
Zinc selenide	FT-IR	Determination of metal ions <i>via</i> chelating agents immobilized at the waveguide surface	$\text{Cu}^{2+}$	40
Silver halide	FT-IR	Trace detection of aromatic hydrocarbons <i>via</i> fiber-coupled planar polymer-coated silver halide transducers	Benzene, toluene, <i>o</i> -, <i>m</i> -, <i>p</i> -xylene	41
Silver halide	FT-IR	Deep-sea MIR sensor coupling polymer-coated silver halide transducers to submersible FT-IR systems	1,2-Dichlorobenzene (DCB), tetrachloroethylene (TeCE), <i>o</i> -, <i>m</i> -, <i>p</i> -xylene	42 and 43
Silver halide	FT-IR	Studying the mechanisms of gas hydrate formation under simulated deep sea conditions	Propane clathrate (with SDS)	44
Silver halide	FT-IR	Detection of oil-in-water with uncoated and epoxidized polybutadiene-coated silver halide transducers	Crude oil	45
Silver halide	FT-IR	Detection of water-in-oil with uncoated and polyacrylic acid-coated silver halide transducers	Water	46
Zinc selenide, silver halide	FT-IR	Analysis of oil constituents dissolved in water <i>via</i> polymer-coated waveguides	Benzene, toluene, <i>o</i> -, <i>m</i> -, <i>p</i> -xylene, ethylbenzene, naphthalene	47
Silver halide	FT-IR	General analysis of biomedical samples with waveguide-based MIR sensing techniques	Skin tissues, biopsy samples, urine, blood, microdialysates	48
Zinc selenide	FT-IR	Selective detection of amino acids <i>via</i> selective ligands immobilized at the waveguide surface	Tyrosine, arginine	49 and 50
Hollow waveguides	FT-IR	Environmental and workplace health gas phase trace monitoring with fiberoptic hollow waveguides with/without preconcentration	Benzene, toluene, <i>o</i> -xylene, ethylbenzene, trichloroethylene, ethene	51–53
Various MIR waveguides	FT-IR, TDL, QCL	Summary on relevant volatile breath constituents and review on breath gas analysis with MIR sensing devices	Various	54 and 55
Hollow waveguides	FT-IR, QCL	Breath gas analysis with hollow waveguides coupled to FT-IR and broadly tunable QCLs	$^{12}\text{CO}_2$ and $^{13}\text{CO}_2$	56–58
GaAs/AlGaAs	QCL	On-chip MIR sensor technology based on semiconductor thin-film waveguides	Acetic anhydride, water	59–61

FT-IR – Fourier transform infrared spectrometer. ATR – attenuated total reflection. MIR – mid-infrared. QCL – quantum cascade laser. FIB – focused ion beam. SDS – sodium dodecyl sulfate. TDL – tunable diode laser.

a sol-gel layer, *etc.* decorating the active transducer/waveguide surface. Besides comparatively simple attachment strategies, membrane-based chemical sensors take advantage of enriching/preconcentrating molecules within the chemical recognition layer, thereby capitalizing on chemical signal amplification strategies. As shown in Fig. 6, this entails accumulating molecules within the probed analytical volume (*i.e.*, in most cases the evanescent field emanating at the waveguide surface). Consequently, a membrane thickness of few micrometers is required; if in addition the membrane is hydrophobic, water – as

an interfering molecule – is largely excluded from the analytically probed volume. The background interference is efficiently reduced, which in turn benefits the SNR. Of course, such chemical amplification may be complemented by additional optical enhancement, as shown in Section 6.3 by using flat-tapered waveguide segments. Finally, the spectral characteristics of polymer or sol-gel membranes provide for a constant and relatively simple spectral background, which still provides sufficient transparency in the MIR regime for detecting analytes of interest.

## 6.2 Security and surveillance

Despite the inherent molecular selectivity, only few waveguide-based MIR sensors claim applications in safety, homeland security, and surveillance applications. Why is that the case?

The main issue when considering such applications – besides the to date rather limited portability – remains associated with a limitation that (in the humble opinion of the author) most other chem/bio sensing schemes also suffer from: chem/bio sensors are usually so-called point sensing devices. Considering the 'analytical field-of-view' of a transducer with dimensions as large as 10 cm or as small as 100  $\mu\text{m}$ , it is immediately evident that only a very localized measurement may be performed recruiting molecules from the vicinity of the transducer. Hence, considering surveillance of large spaces or even open spaces with respect to the release of *e.g.*, toxic chemicals or for explosives monitoring at locations including airports, train stations, or subway platforms – not even speaking of open stadium scenarios, *etc.* – one has to consider distributing hundreds if not thousands of sensors for providing a surveillance network that would capture a localized adverse event. Even if used as additional alarm sensors, it is highly questionable whether a localized measurement may be performed in such a strategically selected location that is indeed representative for the large area or volume under observation.

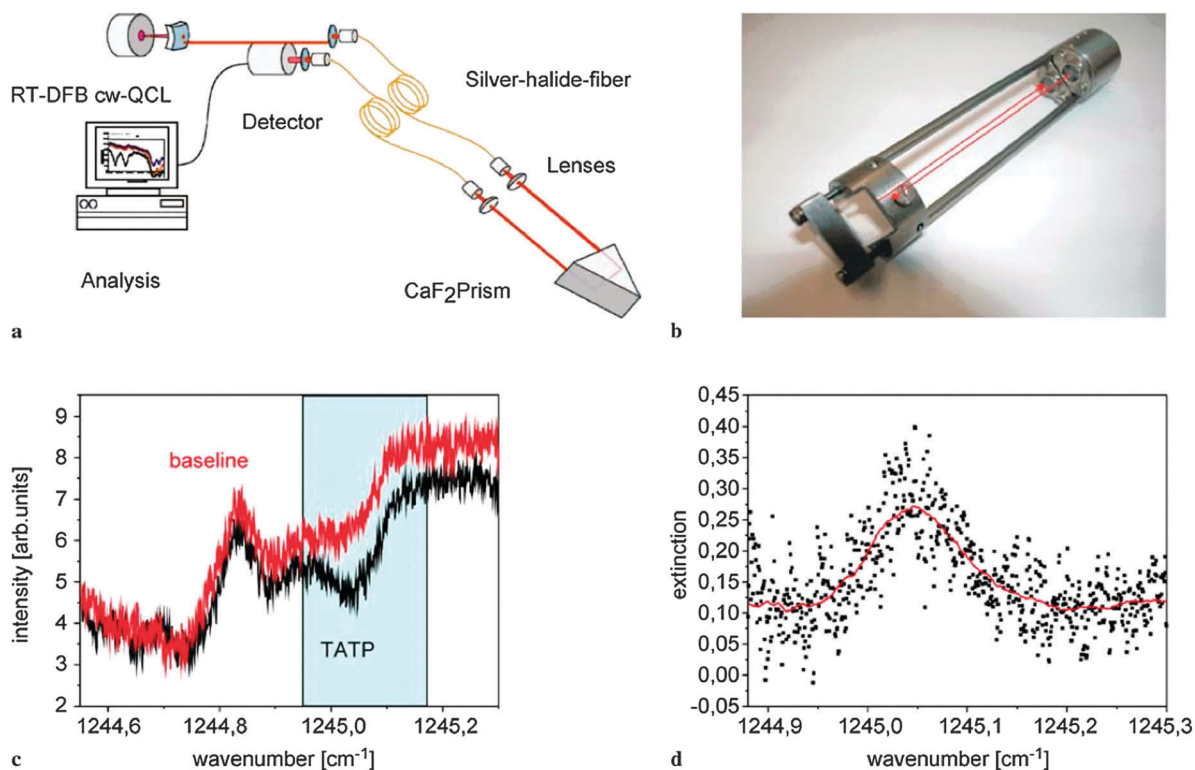
Hence, the only useful deployment scenarios for such point sensing systems may be limited to monitoring restricted access areas or supplies, *i.e.*, if *e.g.* in a building safety monitoring

scenario the entire water or air supply is centrally delivered and distributed, thus offering strategic locations for monitoring the majority of the sample in a representative way despite using a highly localized sensing system.

Albeit being proposed for such surveillance applications to date, it is much more likely that such devices have a practical impact if used by *e.g.*, first responders or in-field military personnel reacting to events that are localized by nature. Exemplarily, Bauer *et al.* have coupled a quantum cascade laser *via* silver halide fibers to an ATR prism, which enabled the detection of triacetone triperoxide (TATP) with a device of hand-held size (Fig. 10).<sup>31</sup> While the principal feasibility has been demonstrated, reports on the analytical figures-of-merit and potential airborne interferences remain to be reported.

## 6.3 Water quality

A major field of application for waveguide-based MIR sensors is the detection of volatile organic constituents (VOCs) and bacterial pathogens in aqueous matrices with potential usage in environmental analysis and water quality monitoring.<sup>32</sup> Of particular interest is the detection of species that are difficult to detect after sampling (*e.g.*, aromatic hydrocarbons (AHCs) such as benzene, toluene, and the xylenes or chlorinated hydrocarbons (CHCs) such as tetrachloroethylene, chlorobenzenes, *etc.*),<sup>33</sup> as they rapidly partition into the supernatant atmosphere or *e.g.*, into the wall material of the sampling device. As previously discussed, appropriate modification of waveguide surfaces with chemical



**Fig. 10** MIR open path absorption sensor for TATP detection. (a) Sensor setup, (b) image of the sensor head, (c) tuning characteristics of the quantum cascade laser and raw data for the absorption of TATP, and (d) evaluated extinction of the TATP signal at approx.  $\lambda = 8 \mu\text{m}$  using the raw data from (c). Reproduced and adapted with permission from ref. 31.



recognition interfaces reduces the spectral water background and allows for the discrimination of water pollutants with sufficient SNR even in complex real-world samples. However, to date none of the reported studies have discussed the long-term stability of such sensors, if continuously deployed for extended measurement periods in real-world scenarios, *e.g.*, rivers, lakes, aquifer systems, *etc.* Yet, most devices utilize a transducer configuration that facilitates rapid exchange of the active sensor head, thus mitigating potential effects of bio-fouling, surface contamination, or degradation of the molecular recognition interface.

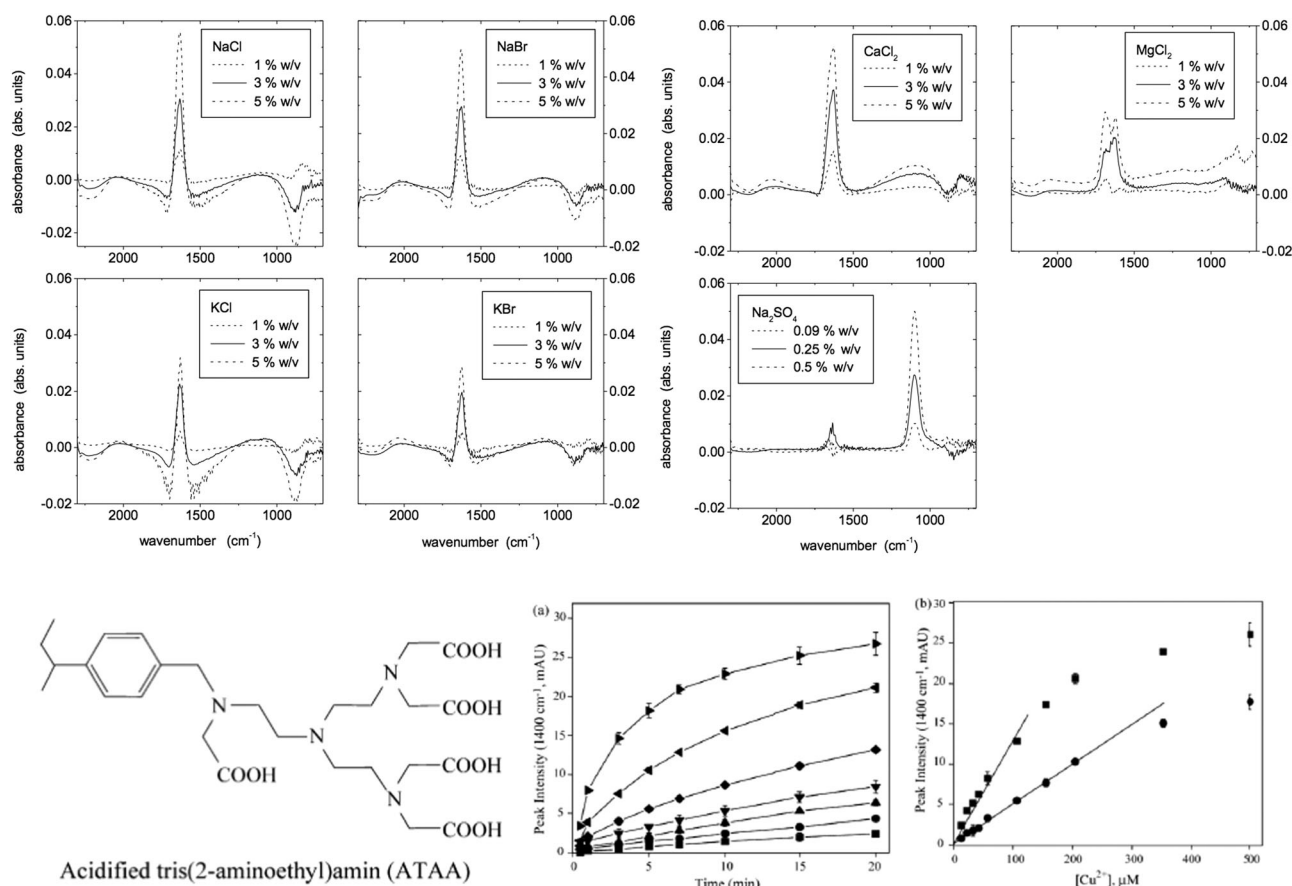
In 2005, the first combination of QCLs with silver halide waveguides for aqueous phase sensing was reported. While Chen *et al.* have used unclad silver halide fibers for analyzing the chemical composition of liquid droplets (*i.e.*, organic constituents in water) at percentage concentration levels,<sup>34</sup> Charlton *et al.* have introduced the first thin-film planar silver halide waveguide segments facilitating the detection of 80.7  $\mu\text{g}$  of urea and 0.01  $\mu\text{L}$  of acetic anhydride present at the waveguide surface.<sup>35</sup> Later, Dekel and Katzir and Schaedle *et al.* further refined the concept of efficiently coupling MIR radiation into such planar silver halide waveguides by integrating

first reflective gratings and then grating couplers micro-fabricated *via* focused ion beam (FIB) milling at the surface of the waveguide slab.<sup>36,37</sup>

One of the few examples of functional MIR biosensors has been demonstrated by Yu *et al.* by immobilizing antibodies (*i.e.*, human IgG, anti-*E. coli* O157:H7, and anti-Salmonella) complexes *via* thiol-linking to 20 nm-thick gold islands decorating the surface of Ge-containing chalcogenide glass waveguides.<sup>38</sup> In this approach, label-free detection and discrimination of bacterial targets was achieved for *E. coli* and *S. enteritidis*, thereby confirming that the concept of MIR bioassays is indeed feasible.

Two rather exotic albeit highly interesting concepts of MIR evanescent field sensors discuss the detection of species without inherent vibrational signature (Fig. 11).

In neat seawater, eight types of ions are prevalent at millimolar or higher concentrations, *i.e.*,  $\text{Cl}^-$ ,  $\text{Na}^+$ ,  $\text{SO}_4^{2-}$ ,  $\text{Mg}^{2+}$ ,  $\text{Ca}^{2+}$ ,  $\text{K}^+$ ,  $\text{Br}^-$ , and  $\text{HCO}_3^-$ , whereby the first six species contribute >99% of the salinity (in order); bicarbonate is rapidly decomposed *via* biological activity, while  $\text{HCO}_3^-$  is considered a minor constituent. Of the dominant ions, only  $\text{SO}_4^{2-}$  has an inherent IR signature. In a seminal study, Vogt *et al.* have shown that once ions dissolve and are hydrated with a shell of



**Fig. 11** (top) Influence of various concentrations of salts on the water absorption band shape shown as difference spectra against deionized water as reference. (bottom left) Chemical structure of the sensing membrane based on acidified tris(2-aminoethyl)amine (ATAA). (bottom middle) Detection time profiles based on the signal at approx.  $1400 \text{ cm}^{-1}$  for concentrations of copper ions of 5 to  $500 \mu\text{M}$  at pH 6. Each point was averaged from triplicate runs. One standard deviation is shown for each data point. (bottom right) Relationship between the obtained IR signals and the concentration of copper ions (recorded after detection of 5 and 20 min, respectively). Reproduced and adapted with permission from ref. 39 and 40.



water molecules, they interact with the surrounding water matrix, which cause significant changes of the hydrogen-bond network of liquid water.<sup>39</sup> These changes directly reflect in the evanescent field absorption spectrum of water, whereby each ion differently affects the bulk water structure, which facilitates the quantitative analysis of individual ionic species at concentrations below 0.1 mol L<sup>-1</sup> using appropriate multivariate statistics.

In a similar approach, the group of Yang has shown the detection of trace amounts of copper ions – which also provide no inherent vibrational features – *via* a band-shifting technique after interaction with an acidified tris(2-aminoethyl)amine (ATAA) membrane coated onto the surface of an evanescent field sensing element.<sup>40</sup>

As a final example, in a recent study Lu *et al.* have significantly improved the sensitivity of detecting benzene, toluene, and the xylenes in water using a novel silver halide waveguide structure based on a planar active transducer segment with cylindric fiberoptic extensions. Thereby, radiation coupling from a broad band light source (FT-IR spectrometer) was facilitated while taking advantage of an increased sensitivity during evanescent field absorption measurements by maximizing the number of internal reflections within the planar sensing segment. Additionally coating the planar transducer segment with a polymeric enrichment membrane demonstrates the utility of combined chemical and optical amplification strategies, as direct simultaneous quantification of these AHCs at ppb (μg L<sup>-1</sup>) levels has been achieved for the first time.<sup>41</sup>

#### 6.4 Oil and gas

In the past decade, a growing number of publications have demonstrated the potential of utilizing evanescent field MIR sensors under increasingly harsh conditions.

With the first demonstration of deep sea FT-IR spectrometers complemented with polymer-coated fiberoptic evanescent field transducers for sensing chlorinate hydrocarbons in marine settings, the utility of MIR chemosensors for such extreme environments has been confirmed.<sup>42,43</sup>

Thereafter, it has been shown that simulating the deep sea environment within pressure vessels in a laboratory environment providing a feed-through option for fiberoptic waveguides enables unique studies on *e.g.*, the formation of gas hydrates under simulated real-world conditions.<sup>44</sup>

The feasibility of waveguide-based evanescent field sensors for detecting traces of oil-in-water<sup>45</sup> and water-in-oil<sup>46</sup> allows monitoring of environmentally relevant parameters, as well as studying the quality and/or ageing of petroleum products.

MIR transparent silver halide fibers with grafted epoxidized polybutadiene layers were utilized as optical transducers for probing oil-in-water emulsions *via* evanescent field absorption. Thereby, direct chemical sensing of crude oil IR signatures without prior sample preparation at concentration levels as low as 46 ppb was achieved with response times of few seconds. Complementarily, water is a frequent contaminant at trace levels in industrial oils and petroleum products. Using hexane as a model matrix, silver halide fiberoptic waveguides coupled to

a FT-IR spectrometer were coated with tin-crosslinked polyacrylic acid, and then deployed for probing water-in-hexane emulsions. Thereby, detection limits of 10 ppm could be achieved.

Last but not least, Pejic and collaborators have shown an improved concept for directly and rapidly quantifying monocyclic and polycyclic aromatic hydrocarbons (MAHs, PAHs) in oil–water mixtures after enrichment into thin poly(isobutylene) polymer membranes coated onto the surface of an evanescent field transducer.<sup>47</sup>

In summary, the MIR chemosensor technologies discussed herein have significant potential for in-field geochemical mapping and for *in situ* monitoring of concentration profiles for a variety of hydrocarbons in geological formations (*e.g.*, petroleum systems) and marine ecosystems.

#### 6.5 Life sciences and health

Liquid phase sensing in bioanalytics and health relevant applications remain rare utilizing waveguide-enhanced MIR sensing devices. Heise *et al.* have reported on a series of measurements studying various biomedical samples ranging from skin tissues and biopsy samples to bodily fluids such as urine, blood, and microdialysates within *in vitro* settings (*e.g.*, clinical laboratory) for non-invasive diagnostics.<sup>48</sup> In these studies, silver-halide fibers have mostly been used as the active transducer element.

In 2006, Lee and Yang presented an intriguing concept for evanescent field-based sensing of tyrosine in aqueous solution.<sup>49</sup> α-Cyclodextrin was immobilized as a ligand at the surface of a MIR waveguide for selectively attracting tyrosine into the evanescent field. Evaluating the unique absorption feature of tyrosine (at 1500 cm<sup>-1</sup>), the selective detection of tyrosine even in mixtures with amino acids and other interferents was shown with a response time of <10 min and a detection limit of approx. 0.4 μM. This study was later complemented by a variation of the molecular recognition interface using sulfonate capturing groups for selectively attracting arginine (*via* the guanidine moieties).<sup>50</sup>

Detecting molecules in the vapor phase using HWGs coupled to MIR light sources has initially been discussed predominantly for environmental gas analysis.<sup>51,52</sup> However, a first application for workplace health monitoring has demonstrated that the quantitative detection of *e.g.*, benzene at low ppb (v/v) concentration levels is feasible after preconcentration with a thermal sorption–desorption system during field measurements preconcentration.<sup>53</sup>

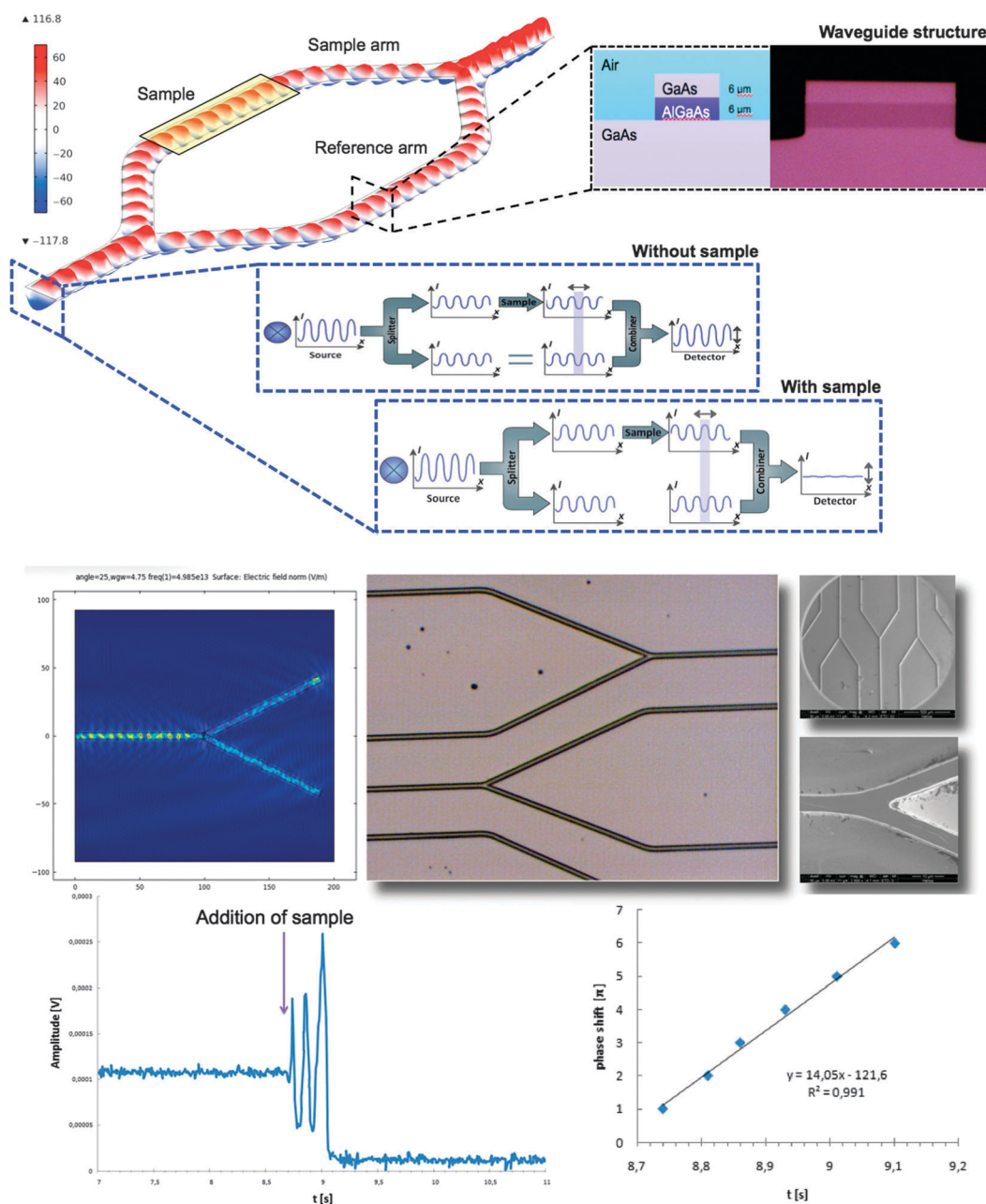
More recently, the potential for analyzing exhaled breath utilizing HWGs coupled with FT-IR spectrometers and QCLs has been explored, thereby revealing significant potential for correlating molecular profiles or fingerprints with certain disease, disease status, or treatment progress. Breath analysis is a long known, yet to date little exploited non-invasive strategy for disease recognition and therapeutic progress monitoring. Without further detailing herein, the quantitative compositional analysis of exhaled breath provides useful biomarker panels characteristic for specific disease conditions invoked by *e.g.*, pulmonary diseases, lung cancer, and breast cancer.<sup>54</sup> The exhaled breath matrix apparently contains comprehensive information on the metabolic state and certain disease pathologies

via patterns of VOCs. Consequently, sensor technologies for advanced breath diagnostics should be capable of molecular discrimination and quantification of selected constituents at ppm–ppb concentration levels, which renders MIR technologies among the methods of choice.<sup>55</sup> So far, it was demonstrated that this sensing concept may be applied for quantitatively discriminating  $^{12}\text{CO}_2$  vs.  $^{13}\text{CO}_2$  in exhaled mouse breath. Analyzing mouse breath samples under real-world conditions by combining either a compact FT-IR spectrometer or a broadly tunable EC-QCL with conventional HWGs, an accuracy and precision comparable to gas chromatography/mass spectrometry as the

gold standard has been achieved.<sup>56–58</sup> Considering the possibility of simultaneously analysing selected VOCs, it is apparent that in future waveguide-enhanced vapour phase sensing platforms operating in the MIR spectral range could complement conventional breath analyzer technologies providing highly relevant molecularly selective information.

## 6.6 Toward MIR bioassays and MIR-lab-on-a-chip

Given the state-of-the-art in MIR sensing applications and considering the current progress based in semiconductor MIR waveguide technology and miniaturization, the development of



**Fig. 12** Schematic working principle of a MIR Mach-Zehnder interferometer (MZI) fabricated on-chip utilizing GaAs/AlGaAs waveguides. The presence of a sample on the measurement arm of the interferometer gives rise to a phase delay vs. the unaffected reference arm, thus resulting in a concentration-dependent change of the observed interference pattern in the time domain.

label-free biodiagnostic devices and lab-on-a-chip concepts operating in the 2.5–20  $\mu\text{m}$  spectral regime appears entirely conceivable.<sup>59</sup> However, a major prerequisite is demonstrating that sample quantities comparable to current microarray platforms (e.g., DNA or protein arrays) operating with sample spot diameters of several tens of micrometers may be addressed. Recent progress demonstrating highly efficient on-chip waveguide structures certainly fertilize the optimistic perspective that such devices are indeed on the horizon.

Taking advantage of the previously discussed GaAs/AlGaAs waveguide technology, Wang *et al.* have recently shown arrays of strip waveguide structures fabricated from epitaxially grown (MOVPE) GaAs/Al<sub>0.2</sub>Ga<sub>0.8</sub>As layers *via* photolithography and reactive ion etching.<sup>60</sup> Coupling of the waveguide array chip to a QCL and using a micro-capillary with a tapered tip for depositing series of 2 nL analyte droplets at the surface of individual waveguide strips, reliable detection of sample volumes as low as 18 pL detecting approx. 20 ng of dissolved acetic anhydride as an exemplary analyte has been demonstrated.

An even more sophisticated transducer has been published by Sieger *et al.* with the first on-chip Mach–Zehnder interferometer operating at MIR wavelengths (Fig. 12).<sup>61</sup> Providing single-mode photon propagation along with excellent surface sensitivity it is anticipated that these devices pave the way toward investigating changes of protein conformation or (bio)-molecular interactions in a label-free bioassay format using minute sample quantities. With the integration of appropriate micro- and nanofluidic architectures, even MIR-lab-on-a-chip concepts appear within reach.

## 7. Conclusions

While waveguide-based mid-infrared chem/bio sensors have come a long way, it is evident that significant quantum leaps in system technology and broadly accepted applications are still ahead. However, the continuous evolution of MIR photonics, on-chip integration, and system miniaturization promises progressively compact sensing and diagnostic platforms ideally taking advantage of the smart combination of chem/bio amplification and optical enhancement schemes. Without doubt, the resulting ‘good vibrations’ may in the true meaning of the words provide a viable solution for *in situ* sensing techniques demanding molecularly discriminatory information without requiring labels or markers.

The author would like to thank all students and scientists who have contributed during recent years to the studies discussed herein. Furthermore, all funding agencies supporting mid-infrared sensor research & technology are greatly acknowledged.

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# EXHIBIT Q



Vladimir Iakovlev, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

IN RE: ETHICON, INC.,	Master File No.
PELVIC REPAIR SYSTEM PRODUCTS	2:12-MD-02327
LIABILITY LITIGATION	MDL 2327

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THIS DOCUMENT RELATES TO CASE  
CONSOLIDATION:

Terreski Mullins, et al., v.  
Ethicon, Inc., et al.  
Case No. 2:12-CV-02952  
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DEPOSITION OF  
VLADIMIR IAKOVLEV, M.D.

\* \* \* \*

HIGHLY CONFIDENTIAL PORTION

\* \* \* \*

September 11, 2015  
9:00 a.m. - 5:05 p.m.

## Vladimir Iakovlev, M.D.

<p style="text-align: right;">Page 2</p> <p>1 Deposition of VLADIMIR IAKOVLEV, M.D.,  2 a witness herein, called for examination by counsel  3 for the Defense, in the above-mentioned matter, the  4 witness having been affirmed, taken at the law  5 offices of Siskinds LLP, 100 Lombard Street,  6 Toronto, Ontario, commencing at 9:03 a.m. on  7 Friday, September 11, 2015, and the proceedings  8 taken down by Stenotype and transcribed by  9 JUDITH M. CAPUTO, RPR, CSR, CRR.</p>	<p style="text-align: right;">Page 4</p> <p>1 INDEX</p> <p>2</p> <p>3 WITNESS: VLADIMIR IAKOVLEV</p> <p>4 PAGE</p> <p>5 DIRECT EXAMINATION BY MR. THOMAS.....5</p> <p>6 CROSS-EXAMINATION BY MR. ORENT.....296</p> <p>7 **Highly Confidential Portion noted on page 40**</p> <p>8</p> <p>9</p> <p>10 INDEX OF EXHIBITS</p> <p>11 NUMBER/DESCRIPTION PAGE NO.</p> <p>12 NO. 1: Expert Report of Dr. Iakovlev in the 5</p> <p>13 Mullins consolidated cases.</p> <p>14 NO. 2: Supplemental Expert Report of 5</p> <p>15 Dr. Iakovlev in the Mullins consolidated cases.</p> <p>16 NO. 3: Notice of Deposition of Dr. Iakovlev. 5</p> <p>17 NO. 4: Thumb drive. 5</p> <p>18 NO. 5: Study Entitled, "Safety Considerations 259</p> <p>19 for synthetic sling surgery."</p> <p>20 NO. 6: Article entitled, "Degradation of 271</p> <p>21 polypropylene in vivo: A microscopic analysis</p> <p>22 of meshes explanted from patients."</p> <p>23 Authored by Vladimir Iakovlev, et al.</p> <p>24</p> <p>25 -- NOTE: Exhibit 4 was retained by Mr. Thomas.</p>
<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S:</p> <p>2</p> <p>3 On Behalf of the Consolidated Plaintiffs:</p> <p>4 JONATHAN ORENT, Esquire</p> <p>5 Motley Rice, LLC</p> <p>6 321 South Main Street, Suite 200</p> <p>7 Providence, Rhode Island 02903</p> <p>8 410.457.7700</p> <p>9 jorent@motleyrice.com</p> <p>10</p> <p>11 On Behalf of the Defendants, Ethicon:</p> <p>12 DAVID B. THOMAS, Esquire</p> <p>13 Thomas, Combs &amp; Spann, PLLC</p> <p>14 300 Summers Street, Suite 1380</p> <p>15 Charleston, West Virginia</p> <p>16 304.414.1807</p> <p>17 dthomas@tcspllc.com</p> <p>18</p> <p>19 M. ANDREW SNOWDEN, Esquire</p> <p>20 Butler Snow, LLP</p> <p>21 The Pinnacle at Symphony Place</p> <p>22 150 3rd Avenue South, Suite 1600</p> <p>23 Nashville, Tennessee 37201</p> <p>24 615.651.6700</p> <p>25 andy.snowden@butlersnow.com</p>	<p style="text-align: right;">Page 5</p> <p>1 EXHIBIT NO. 1: Expert Report of</p> <p>2 Dr. Vladimir Iakovlev in the Mullins</p> <p>3 consolidated cases.</p> <p>4 EXHIBIT NO. 2: Supplemental Expert</p> <p>5 Report of Dr. Vladimir Iakovlev in the</p> <p>6 Mullins consolidated cases.</p> <p>7 EXHIBIT NO. 3: Notice of Deposition of</p> <p>8 Dr. Vladimir Iakovlev.</p> <p>9 EXHIBIT NO. 4: Thumb drive.</p> <p>10</p> <p>11 Whereupon,</p> <p>12 VLADIMIR IAKOVLEV, M.D.,</p> <p>13 called for examination by counsel for Defendant</p> <p>14 and having been affirmed by me, was examined and</p> <p>15 testified as follows:</p> <p>16 DIRECT EXAMINATION BY MR. THOMAS:</p> <p>17 Q. Good morning, Doctor.</p> <p>18 We've met before. My name is David</p> <p>19 Thomas. I'm going to ask you a number of questions</p> <p>20 about your expert witness opinion in the Mullins</p> <p>21 case pending in the MDL in West Virginia; fair</p> <p>22 enough?</p> <p>23 A. Yes.</p> <p>24 Q. I'm going to hand you what I've</p> <p>25 marked as Exhibits 1 and 2 and ask you if Exhibit</p>

2 (Pages 2 to 5)

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Vladimir Iakovlev, M.D.

<p style="text-align: right;">Page 6</p> <p>1 <b>Nos. 1 and 2 are the expert reports that you</b>  2 <b>prepared in the Mullins case.</b>  3 A. Yes, that's correct. This one is  4 on the left, the thicker one, is a combination of  5 several patients and this one on the right, Exhibit  6 No. 2, is a supplemental set of figures  7 specifically from the specimen of Ms. Mullins.  8 <b>Q. And Exhibits No. 1 and 2 represent</b>  9 <b>the complete opinions you're prepared to give in</b>  10 <b>this case; is that fair?</b>  11 A. That's correct.  12 <b>Q. I show you now what's been marked</b>  13 <b>as deposition Exhibit No. 3. That's a Notice of</b>  14 <b>Deposition in this case.</b>  15 A. Yes, I do see it.  16 <b>Q. Have you seen that before today?</b>  17 A. Yes, I did.  18 <b>Q. As a part of Exhibit 3, there's a</b>  19 <b>request attached to it that you produce documents</b>  20 <b>in response to that.</b>  21 A. There are 27 requests. Yes, I've  22 seen that.  23 <b>Q. Did you review those requests?</b>  24 A. Yes, I did.  25 <b>Q. Did you attempt to collect the</b></p>	<p style="text-align: right;">Page 8</p> <p>1 everything I had pertinent to this case.  2 MR. ORENT: Just to clarify though  3 again, the communication, I believe, was outside of  4 the three areas specified on Number 27.  5 MR. THOMAS: I'm sorry, I did not hear  6 you.  7 MR. ORENT: Under the federal rules  8 your request Number 27, to make the federal rule  9 recognizing the privilege existing between expert  10 and attorneys.  11 With the exception of the three areas  12 that you requested, I believe there were no  13 responsive communications specifically to those  14 three areas.  15 I believe other communications exist  16 that are not discoverable, and that's what the  17 doctor is referring to.  18 MR. THOMAS: Okay.  19 MR. ORENT: I don't believe he withheld  20 anything responsive to the request as written.  21 BY MR. THOMAS:  22 <b>Q. Doctor, you've given depositions</b>  23 <b>before in the Ethicon MDL, correct?</b>  24 A. That is correct.  25 <b>Q. You've testified in connection</b></p>
<p style="text-align: right;">Page 7</p> <p>1 <b>information contained in those requests and produce</b>  2 <b>it to me today?</b>  3 A. Yes, I gathered all what I could  4 on the thumb drive.  5 <b>Q. And counsel has given me today</b>  6 <b>what I've marked as Exhibit No. 4, which is a thumb</b>  7 <b>drive. Is this the thumb drive that you just</b>  8 <b>described where you attempted to load all of the</b>  9 <b>documents responsive to the Notice of Deposition</b>  10 <b>that you could find to put on the thumb drive?</b>  11 A. That is correct.  12 MR. ORENT: At this point I want to  13 place an objection and notification. We did file a  14 written objection so subject to those written  15 objections that material has been produced.  16 BY MR. THOMAS:  17 <b>Q. To save the time of going through</b>  18 <b>the notice or the thumb drive for right now, can</b>  19 <b>you recall any documents responsive to the Notice</b>  20 <b>of Deposition that you did not include on the thumb</b>  21 <b>drive?</b>  22 A. Well, the communication with  23 lawyers I didn't put.  24 <b>Q. Okay.</b>  25 A. The rest, I think I included</p>	<p style="text-align: right;">Page 9</p> <p>1 <b>with the Bellew case?</b>  2 A. Yes, I did.  3 <b>Q. And you've testified in connection</b>  4 <b>with the Huskey and Edwards cases, correct?</b>  5 A. That is correct.  6 <b>Q. And in those depositions you</b>  7 <b>testified to a methodology that you used to collect</b>  8 <b>specimens, create histopathological slides where</b>  9 <b>appropriate and review those slides.</b>  10 <b>Did you follow the same process in the</b>  11 <b>Mullins case that you followed in the Bellew and</b>  12 <b>Huskey Edwards cases?</b>  13 A. The process is standard. It's not  14 specifically for medical-legal cases or mesh cases.  15 It's a standard histology protocols in a diagnostic  16 pathology lab, so I don't change it. I follow them  17 for each specimen regardless if it's medical-legal  18 or a regular hospital patient.  19 <b>Q. Doctor, my question really meant</b>  20 <b>to eliminate re asking all those questions that</b>  21 <b>were asked in Huskey, Edwards and Bellew.</b>  22 <b>And if we can confirm that you followed</b>  23 <b>the same procedures in the Mullins case that you</b>  24 <b>followed in the prior depositions where you were</b>  25 <b>asked about your procedures then I'm not going to</b></p>

3 (Pages 6 to 9)

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Vladimir Iakovlev, M.D.

<p style="text-align: right;">Page 10</p> <p>1 go over that again. Can we confirm that you</p> <p>2 followed the same steps?</p> <p>3 A. Yes, I can confirm that.</p> <p>4 Q. Doctor, what is a neuropathologist?</p> <p>5 A. Neuropathologist?</p> <p>6 Q. Yes.</p> <p>7 A. Neuropathologist is a surgical</p> <p>8 pathologist who is specializing in examining brain</p> <p>9 tissue or spinal cord. Sometimes it's the</p> <p>10 subspecialty people do just neuropathology;</p> <p>11 sometimes there is cross-coverage.</p> <p>12 In our institution we have a</p> <p>13 neuropathologist but it's only one. Sometimes he</p> <p>14 goes away on meetings, so we cover neuropathology.</p> <p>15 Q. Are you a neuropathologist?</p> <p>16 A. I'm cross-covering neuropathology</p> <p>17 when he is away but I have not specialized in</p> <p>18 neuropathology.</p> <p>19 Q. Are you board certified in</p> <p>20 neuropathology?</p> <p>21 A. No, and you don't have to be board</p> <p>22 certified in neuropathology because surgical</p> <p>23 pathology includes neuropathology.</p> <p>24 I mean, you can sub specialize further</p> <p>25 down, but it depends on specific institution.</p>	<p style="text-align: right;">Page 12</p> <p>1 transvaginal. I mean, why would I consult a</p> <p>2 neuropathologist?</p> <p>3 Q. Just a simple yes or no question?</p> <p>4 A. No, I didn't. There was no</p> <p>5 purpose.</p> <p>6 Q. Did you consult any neuropathology</p> <p>7 textbooks in connection with your opinions in this</p> <p>8 case?</p> <p>9 A. Specifically just recently?</p> <p>10 Q. Any time during your work in this</p> <p>11 case?</p> <p>12 A. Not in this case. I opened and</p> <p>13 read several neuropathology books when I was doing</p> <p>14 research in meshes. It's not just neuropathology</p> <p>15 books, I mean, neuropathology is described in</p> <p>16 general surgical pathology books. Because I've</p> <p>17 been in this field for three years.</p> <p>18 Q. I understand. Just specific</p> <p>19 questions, we'll get done quicker if you answer</p> <p>20 "yes" or "no", if you can, and I'm not trying to</p> <p>21 pin you down.</p> <p>22 Is it your belief that neuropathology</p> <p>23 has no role in understanding the presence of nerves</p> <p>24 in the pelvic floor?</p> <p>25 MR. ORENT: Objection to form.</p>
<p style="text-align: right;">Page 11</p> <p>1 Because some institutions have a large number of</p> <p>2 specialized cases and some institutions they cover</p> <p>3 broad range.</p> <p>4 Q. You said you had a</p> <p>5 neuropathologist at St. Michael's?</p> <p>6 A. Yes, we do.</p> <p>7 Q. What is the person's name?</p> <p>8 A. Dr. David Munoz.</p> <p>9 Q. Is that the only neuropathologist</p> <p>10 at St. Michael's?</p> <p>11 A. Right now, yes.</p> <p>12 Q. Did you consult with Doctor --</p> <p>13 what's his last name?</p> <p>14 A. Munoz.</p> <p>15 Q. M-U-N-O-Z?</p> <p>16 A. Yes.</p> <p>17 Q. Did you consult with Dr. Munoz in</p> <p>18 connection with any of the opinions that you've</p> <p>19 given in this case?</p> <p>20 A. No.</p> <p>21 Q. Did you consult with any</p> <p>22 neuropathologist in connection with the opinions</p> <p>23 you've given in this case?</p> <p>24 A. We're not talking about brain</p> <p>25 tumors; we're talking about sub tissue</p>	<p style="text-align: right;">Page 13</p> <p>1 THE WITNESS: Yeah, actually the form</p> <p>2 of the question is quite bizarre.</p> <p>3 Because neuropathology is part of</p> <p>4 surgical pathology. So I'm a surgical pathologist</p> <p>5 I'm examining -- yes, there is a field of</p> <p>6 neuropathology when you specialize in that.</p> <p>7 If you take a combination of peripheral</p> <p>8 nerves as part of neuropathology, then I can say</p> <p>9 yes, there is a part of neuropathology. But as I</p> <p>10 said, it's still within surgical pathology.</p> <p>11 This separation is somewhat artificial.</p> <p>12 You probably don't understand exactly how such</p> <p>13 specialization works. Probably that's where it's</p> <p>14 coming from.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Perhaps. Do you know a Kenneth</p> <p>17 Aldape, A-L-D-A-P-E?</p> <p>18 A. No.</p> <p>19 Q. Lorraine Kalia, K-A-L-I-A?</p> <p>20 A. No.</p> <p>21 Q. Julia Keith?</p> <p>22 A. No.</p> <p>23 Q. Tim Rasmus Kiehl, K-I-E-H-L?</p> <p>24 A. The names might be similar. I</p> <p>25 mean, a couple of those names are the same as a</p>

4 (Pages 10 to 13)



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<p style="text-align: right;">Page 14</p> <p>1 couple of neuropathologists in Toronto, I believe,</p> <p>2 but I don't know their first names.</p> <p>3 <b>Q. My information is these</b></p> <p>4 <b>neuropathologists are affiliated with the</b></p> <p>5 <b>University of Toronto.</b></p> <p>6 A. Yes, so Dr. Kiehl is practicing at</p> <p>7 UHN and I think there was another name that also</p> <p>8 practices at UHN. It's a different institution.</p> <p>9 The U of T affiliated hospital is called UHN.</p> <p>10 <b>Q. There's special neuropathology</b></p> <p>11 <b>journals, aren't there?</b></p> <p>12 A. Yes, there are.</p> <p>13 <b>Q. Do you subscribe to any?</b></p> <p>14 A. No.</p> <p>15 <b>Q. So fair to say you don't serve on</b></p> <p>16 <b>the editorial board of any neuropathology journals,</b></p> <p>17 <b>true?</b></p> <p>18 A. No, that's true.</p> <p>19 <b>Q. Is there any reason for you to</b></p> <p>20 <b>consult with a neuropathologist to understand how</b></p> <p>21 <b>nerves function in the pelvic floor?</b></p> <p>22 A. Not really. The only reason I</p> <p>23 would go to a neuropathologist when there is</p> <p>24 something I don't know and I cannot find answers in</p> <p>25 regular books, something which comes from</p>	<p style="text-align: right;">Page 16</p> <p>1 <b>Q. And what question did you ask him?</b></p> <p>2 <b>What stain do you use for what?</b></p> <p>3 A. When we started our research in</p> <p>4 meshes, the question was, if the nerve's ingrown.</p> <p>5 So this is kind of basic question.</p> <p>6 <b>Q. Sorry, if the nerves what?</b></p> <p>7 A. Grow into the mesh. So this was a</p> <p>8 basic question. But then I was thinking, okay, so</p> <p>9 I need to make sure that I'm not missing anything</p> <p>10 and I started thinking of possible scenarios, how</p> <p>11 nerves can be affected by the mesh.</p> <p>12 Are they going atrophic, can they</p> <p>13 disappear completely? And if they go atrophic, you</p> <p>14 can see atrophy in the nerve with any stain,</p> <p>15 because the area becomes empty, sort of ooze, the</p> <p>16 Schwann cells disappear, their axons, this is a</p> <p>17 basic knowledge.</p> <p>18 And I ask him if he's using something</p> <p>19 else, and he was using exactly what I was using.</p> <p>20 <b>Q. So is it fair to understand that</b></p> <p>21 <b>you confirmed with Dr. Munoz your choice of the</b></p> <p>22 <b>S100 stain for nerves?</b></p> <p>23 A. No, that was not about the S100.</p> <p>24 <b>Q. What stain specifically was it</b></p> <p>25 <b>about?</b></p>
<p style="text-align: right;">Page 15</p> <p>1 experience. We are talking about basic function.</p> <p>2 <b>Q. In Canada, is there a board</b></p> <p>3 <b>certification for your position as anatomical</b></p> <p>4 <b>pathologist?</b></p> <p>5 A. Yes, there is.</p> <p>6 <b>Q. Is there a board certification for</b></p> <p>7 <b>neuropathologists?</b></p> <p>8 A. I'm not sure, but we are</p> <p>9 practicing neuropathology with this anatomical</p> <p>10 pathology certification.</p> <p>11 <b>Q. As far as you recall, you haven't</b></p> <p>12 <b>consulted with any neuropathologists in connection</b></p> <p>13 <b>with your work in this mesh litigation; fair?</b></p> <p>14 MR. ORENT: Objection.</p> <p>15 THE WITNESS: Not for this specific</p> <p>16 case. Earlier, when I started research, I ask a</p> <p>17 few questions which stain sometimes it was better</p> <p>18 to use when there is pathology of nerves.</p> <p>19 BY MR. THOMAS:</p> <p>20 <b>Q. Who did you ask?</b></p> <p>21 A. Dr. Munoz, but I think it was even</p> <p>22 before the litigation started.</p> <p>23 <b>Q. And what did you ask Dr. Munoz?</b></p> <p>24 A. Which stains he was using, if he</p> <p>25 was using something different that I was using.</p>	<p style="text-align: right;">Page 17</p> <p>1 A. If anything else he's using to</p> <p>2 examine nerve atrophy or degeneration.</p> <p>3 <b>Q. And what were you using to analyze</b></p> <p>4 <b>that question?</b></p> <p>5 A. Just locating H&amp;E.</p> <p>6 <b>Q. And Dr. Munoz said that was what</b></p> <p>7 <b>he was using to analyze the same question?</b></p> <p>8 A. He said that you can see it on</p> <p>9 H&amp;E, but there are a number of other stains to</p> <p>10 examine for nerve atrophy.</p> <p>11 <b>Q. And what stains did he tell you</b></p> <p>12 <b>that you could use, other than H&amp;E?</b></p> <p>13 A. Well, you can see some of the</p> <p>14 atrophy on S100 -- I don't remember exactly what he</p> <p>15 said because it was three years ago, because now</p> <p>16 what I remember it might be coming from different</p> <p>17 sources, so from my own experience.</p> <p>18 <b>Q. Do you have a specific</b></p> <p>19 <b>recollection of talking to any neuropathologist who</b></p> <p>20 <b>gave you any information about how to conduct your</b></p> <p>21 <b>investigation into these meshes?</b></p> <p>22 A. I don't understand your question.</p> <p>23 <b>Q. You've told me about conversation</b></p> <p>24 <b>you had with Dr. Munoz. Do you have a specific</b></p> <p>25 <b>recollection, you remember having any conversations</b></p>

5 (Pages 14 to 17)

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<p style="text-align: right;">Page 18</p> <p>1 with any neuropathologists about how to conduct</p> <p>2 your work in these cases?</p> <p>3 A. Why would I?</p> <p>4 Q. I'm just asking you if you did or</p> <p>5 not?</p> <p>6 A. No, I didn't.</p> <p>7 Q. Thank you. Now, Exhibit No. 1 and</p> <p>8 Exhibit No. 2 are your reports in this case; we</p> <p>9 talked about that already. They contain a number</p> <p>10 of images?</p> <p>11 A. That's correct.</p> <p>12 Q. Have you supplied copies of all</p> <p>13 those images on this thumb drive?</p> <p>14 A. No, because they're already</p> <p>15 included in the report. I can produce them for you</p> <p>16 separately.</p> <p>17 Q. Do you have digital images of the</p> <p>18 slides in this report?</p> <p>19 A. Of course.</p> <p>20 Q. But they're not on the thumb</p> <p>21 drive?</p> <p>22 A. No, because they're already in the</p> <p>23 report.</p> <p>24 Q. Do you have images of the tissue</p> <p>25 samples that are contained in the report that are</p>	<p style="text-align: right;">Page 20</p> <p>1 Q. Okay. And from what tissue</p> <p>2 samples did you take them?</p> <p>3 A. From explanted TVT and</p> <p>4 TVT-O meshes.</p> <p>5 Q. How many TVT?</p> <p>6 A. Oh, that I would have to check</p> <p>7 with my records now. I don't remember now.</p> <p>8 Q. And TVT-O?</p> <p>9 A. It's there, but I don't remember</p> <p>10 now.</p> <p>11 Q. And the TVT and the TVT-O</p> <p>12 specimens that are contained in your report are</p> <p>13 that, are those specimens from the set of specimens</p> <p>14 that you obtained from Dr. Klinge?</p> <p>15 A. No. It's a combination of earlier</p> <p>16 medical-legal cases, patients of St. Michael's</p> <p>17 Hospital, and samples which came within this</p> <p>18 consolidated trial.</p> <p>19 The earlier cases came from different</p> <p>20 law firms.</p> <p>21 Q. Do you know what I'm referring to?</p> <p>22 You talked about the Bellew case, the set of slides</p> <p>23 that you received from Dr. Klinge, and Dr.</p> <p>24 Kreutzer, 22 TVT and TVT-O samples?</p> <p>25 A. My recollection is I was contacted</p>
<p style="text-align: right;">Page 19</p> <p>1 not in the report?</p> <p>2 A. But we took those images together</p> <p>3 with your expert.</p> <p>4 Q. I'm just asking you if you have</p> <p>5 them?</p> <p>6 A. I should have them, yeah.</p> <p>7 Q. Okay?</p> <p>8 A. Because we were taking them -- he</p> <p>9 would take picture. I would take picture of the</p> <p>10 same field.</p> <p>11 Q. But there are images that you have</p> <p>12 of the tissue samples that are contained in your</p> <p>13 report that are not produced on this thumb drive,</p> <p>14 correct?</p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: There should be. I was</p> <p>17 not using them. I was just recording together with</p> <p>18 your expert when I received the specimens.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Okay. And if you go to -- let me</p> <p>21 just ask this question.</p> <p>22 What is the source of the images that</p> <p>23 are contained in your report? Where did you get</p> <p>24 them?</p> <p>25 A. I took them.</p>	<p style="text-align: right;">Page 21</p> <p>1 by Anderson Law and I'm not sure when -- I don't</p> <p>2 remember exactly where the package came from, but</p> <p>3 all my communication was with the Anderson Law.</p> <p>4 Q. I understand that, Doctor, but in</p> <p>5 the Bellew case you testified at length about a set</p> <p>6 of 22 TVT and TVT-O samples that you had received</p> <p>7 from Mr. Anderson that had previously been reviewed</p> <p>8 by Dr. Kreutzer and by Doctor Klinge?</p> <p>9 A. Kreutzer for sure; I'm not sure</p> <p>10 about Doctor Klinge. There were no records, or</p> <p>11 maybe there was records but I just don't remember</p> <p>12 them.</p> <p>13 I didn't contact specifically Doctor</p> <p>14 Klinge, or he didn't contact me specifically about</p> <p>15 these samples.</p> <p>16 Q. Are the images of the TVT and the</p> <p>17 TVT-O slides that are in your report in this case</p> <p>18 from the same set of slides that Dr. Kreutzer</p> <p>19 reviewed?</p> <p>20 A. Some of them could be. Again, I</p> <p>21 don't remember now. It would be difficult to trace</p> <p>22 them back.</p> <p>23 Q. Do you have somewhere a key that</p> <p>24 shows whose tissue this is in the report?</p> <p>25 A. In the report, the way the images</p>

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<p style="text-align: right;">Page 22</p> <p>1 were saved during my work, they would be usually  2 saved in folders for specific expert report.  3 <b>Q. Let's go to page 19 of your</b>  4 <b>report, please, Exhibit No. 1?</b>  5 A. So if we open these images, I  6 specify if the image is coming from consolidated  7 trial cases, which I received just recently, or if  8 the images are of additional cases, and additional  9 I meant previous TVT and TVT-O cases which I  10 received during the course of my work on expert of  11 possible Bellew case and others.  12 <b>Q. How many consolidated cases do you</b>  13 <b>have images for, individual plaintiffs?</b>  14 A. Like four, three. Three, four.  15 Some specimens came as bare mesh, had difficulty  16 embedding -- well, we embedded them but there was  17 not much in there.  18 <b>Q. I understand. I'm just trying to</b>  19 <b>understand what you're working from.</b>  20 <b>So you have three or four tissue</b>  21 <b>samples from plaintiffs in the consolidated cases,</b>  22 <b>correct?</b>  23 A. That is correct.  24 <b>Q. What kind of mesh is that?</b>  25 A. TVT or TVT-O.</p>	<p style="text-align: right;">Page 24</p> <p>1 embedded surgical number.  2 Because they're all spread within  3 almost three years, some of them can be traced;  4 some of them would be difficult to trace.  5 <b>Q. Is it fair to understand that</b>  6 <b>looking at the report, where you identify images</b>  7 <b>from additional TVT cases, you're unable to tell me</b>  8 <b>from what case that image comes from?</b>  9 MR. ORENT: Objection.  10 THE WITNESS: In some cases I can, and  11 some cases I cannot. I can tell that you all of  12 them came from TVT and TVT-O because I kept strict  13 records for that.  14 But I didn't keep strict records for  15 specific cases, at least at the beginning.  16 BY MR. THOMAS:  17 <b>Q. Okay. In those places where you</b>  18 <b>can identify the patient, did you do so in your</b>  19 <b>report?</b>  20 A. No.  21 <b>Q. Why not?</b>  22 A. But they are not in this trial --  23 and they may be confidential. And why would I?  24 <b>Q. But there are images in this</b>  25 <b>report that don't have identifying information --</b></p>
<p style="text-align: right;">Page 23</p> <p>1 <b>Q. Okay. And so in your report,</b>  2 <b>where you refer to images of consolidated cases, is</b>  3 <b>it fair to say that those images come from the</b>  4 <b>three to four tissue samples that you got from the</b>  5 <b>consolidated cases?</b>  6 A. That's correct.  7 <b>Q. If you go to page 21?</b>  8 A. Yes.  9 <b>Q. Page 21 identifies in Figure Set</b>  10 <b>1c, images of additional TVT cases; what does that</b>  11 <b>mean?</b>  12 A. That means this image comes from  13 previous TVT and TVT-O cases, or cases I received  14 previously.  15 <b>Q. Can you tell by looking at this</b>  16 <b>whether it's a medical-legal or whether it's</b>  17 <b>something that came through St. Michael's?</b>  18 A. It would have to be sort of  19 picture matching. I would have to open the folders  20 which contain previous reports.  21 It all depends how the figure was  22 taken. If it was taken by older camera, it didn't  23 record the case number.  24 Now, for some newer cases the images  25 were scanned and when the scanner works, there is</p>	<p style="text-align: right;">Page 25</p> <p>1 <b>none of them have identifying information?</b>  2 A. They have one single identifying  3 information which is important: TVT or TVT-O.  4 Everything else doesn't matter.  5 <b>Q. But I can't take this, go into</b>  6 <b>your file and figure out where this slide is, can</b>  7 <b>I?</b>  8 A. I'm telling you it's all TVT and  9 TVT-O. What else do you need to know?  10 <b>Q. Am I able to take this thumb drive</b>  11 <b>and figure out which slide is which patient on</b>  12 <b>page 21?</b>  13 MR. ORENT: Objection. I think what  14 the doctor is explaining is that these are all from  15 prior reports served on you.  16 THE WITNESS: Most of them are. You  17 can go to older reports and find them.  18 BY MR. THOMAS:  19 <b>Q. Why didn't you say "from the</b>  20 <b>Edwards case" to tell us where it came from?</b>  21 A. Why would I? I don't understand  22 the question. I mean, this is an opinion about TVT  23 and TVT-O.  24 I am not making an opinion about  25 Edwards or any other specific patient. I am giving</p>

7 (Pages 22 to 25)

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<p style="text-align: right;">Page 26</p> <p>1 you opinion about TVT-O as a product.</p> <p>2 <b>Q. Do you maintain your sets of these</b></p> <p>3 <b>slides by individual plaintiff?</b></p> <p>4 A. In some cases, yes. If there is a</p> <p>5 generated report because that is a specific</p> <p>6 plaintiff, I save them as separate folder.</p> <p>7 But remember those 23 or 22 cases when</p> <p>8 they came as a bulk and I did not produce any</p> <p>9 specific reports for specific patients, individual</p> <p>10 patients. They were all saved in one folder.</p> <p>11 <b>Q. Okay?</b></p> <p>12 A. Which was just additional --</p> <p>13 didn't keep record for that.</p> <p>14 <b>Q. Are the files on this thumb drive,</b></p> <p>15 <b>Exhibit 4, marked by individual plaintiff?</b></p> <p>16 A. No. As I said, I didn't include</p> <p>17 figures because they were included in the report</p> <p>18 already.</p> <p>19 If you want me to include these</p> <p>20 specific figures, I can do that. But it will not</p> <p>21 be possible to trace specific picture, specific</p> <p>22 patient.</p> <p>23 And that was not the purpose because</p> <p>24 the purpose was to give an opinion about TVT-O or</p> <p>25 TVT as a product, not to give opinion for specific</p>	<p style="text-align: right;">Page 28</p> <p>1 <b>Q. For the original tissue samples</b></p> <p>2 <b>that you received from Dr. Kreutzer, the 22 or 23</b></p> <p>3 <b>TVT or TVT-O, did you know that those samples,</b></p> <p>4 <b>tissue samples, were also analyzed by Dr. Jordi,</b></p> <p>5 <b>using analytical chemistry?</b></p> <p>6 A. The name sounds familiar but I</p> <p>7 don't know details. I don't remember, sorry. I</p> <p>8 don't remember specific details, what was done in</p> <p>9 that time.</p> <p>10 <b>Q. Have you ever seen any analytical</b></p> <p>11 <b>chemistry testing on the 22 or 23 TVT samples that</b></p> <p>12 <b>you received from Dr. Kreutzer?</b></p> <p>13 A. I don't recall specific details.</p> <p>14 I could have seen something, I could have not, it's</p> <p>15 been quite a long time ago.</p> <p>16 <b>Q. Did you ever request that</b></p> <p>17 <b>analytical chemistry testing be conducted on any of</b></p> <p>18 <b>the mesh samples that you've analyzed?</b></p> <p>19 A. No. I have my own methodology in</p> <p>20 this; I describe what I see. Why would I ask</p> <p>21 somebody else to do something else?</p> <p>22 <b>Q. So is it fair to understand that</b></p> <p>23 <b>for Exhibits Number 1 and 2, which is your report</b></p> <p>24 <b>and supplemental report, that all of the images in</b></p> <p>25 <b>here are TVT or TVT-O manufactured by Ethicon?</b></p>
<p style="text-align: right;">Page 27</p> <p>1 plaintiffs.</p> <p>2 <b>Q. Exhibit No. 2 is a supplemental --</b></p> <p>3 <b>micro photographs. You identify those as from the</b></p> <p>4 <b>specimen of Ms. Elizabeth Mullins?</b></p> <p>5 A. That is correct.</p> <p>6 <b>Q. Is Elizabeth Mullins -- strike</b></p> <p>7 <b>that. Did you share this tissue with Ethicon?</b></p> <p>8 A. Yes, I mailed it a week ago.</p> <p>9 <b>Q. Why did you identify this by</b></p> <p>10 <b>patient name and not identify the others in your</b></p> <p>11 <b>report by patient name?</b></p> <p>12 A. Because it was a single case</p> <p>13 specifically supplemented for one specific patient.</p> <p>14 <b>Q. So this is one of the three or</b></p> <p>15 <b>four TVT, TVT-O cases that you reviewed for</b></p> <p>16 <b>consolidated plaintiffs?</b></p> <p>17 A. Might be an additional to the</p> <p>18 three or four.</p> <p>19 <b>Q. Okay?</b></p> <p>20 A. So it could be fifth, or fourth.</p> <p>21 <b>Q. Okay. Do you expect to receive</b></p> <p>22 <b>any more tissue samples from the consolidated</b></p> <p>23 <b>plaintiffs?</b></p> <p>24 A. No. As far as I would understand</p> <p>25 this is all what we have at this point.</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Yes. Some images were taken from</p> <p>2 publications, so there was one or two panels from</p> <p>3 different mesh manufacturer.</p> <p>4 But the rest, when the pictures were</p> <p>5 individual, they were all of TVT or TVT-O explanted</p> <p>6 specimens.</p> <p>7 <b>Q. Are you able to tell me sitting</b></p> <p>8 <b>here today -- strike that.</b></p> <p>9 <b>Let's go to Exhibit 3, please. Number</b></p> <p>10 <b>15?</b></p> <p>11 A. Yes.</p> <p>12 <b>Q. Number 15 asks for all materials</b></p> <p>13 <b>including but not limited to any protocol</b></p> <p>14 <b>specimens, slide raw data interim and final test</b></p> <p>15 <b>results, log laboratory books, notes, photographs,</b></p> <p>16 <b>photo micrographs and any other documents relating</b></p> <p>17 <b>to the pristine polypropylene control you tested by</b></p> <p>18 <b>exposure to formalin for up to four months</b></p> <p>19 <b>referenced on page 17 of your report in this case.</b></p> <p>20 <b>Is there any information on the thumb</b></p> <p>21 <b>drive from Exhibit 4 for that?</b></p> <p>22 A. The entire protocol is really</p> <p>23 simple. It was included in the paper, so it is on</p> <p>24 the thumb drive; the paper is on the thumb drive.</p> <p>25 I didn't have anything in addition to that.</p>

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<p style="text-align: right;">Page 30</p> <p>1 <b>Q. Is there any lab notebook?</b></p> <p>2 A. No, I mean --</p> <p>3 <b>Q. Are there any photographs?</b></p> <p>4 A. All photographs I had, I included</p> <p>5 there.</p> <p>6 <b>Q. So whatever you have related to</b></p> <p>7 <b>the formalin exposed polypropylene control is on</b></p> <p>8 <b>the thumb drive?</b></p> <p>9 A. In the report. The pictures are</p> <p>10 on the report. The paper with description of the</p> <p>11 experiment is on the thumb drive.</p> <p>12 <b>Q. What kind of polypropylene was</b></p> <p>13 <b>tested with formalin?</b></p> <p>14 A. What do you mean, what kind? I</p> <p>15 tested meshes of different manufacturers including</p> <p>16 Ethicon TVT.</p> <p>17 <b>Q. So you did use an Ethicon Prolene</b></p> <p>18 <b>mesh in the formalin control test?</b></p> <p>19 A. It was TVT.</p> <p>20 <b>Q. Okay.</b></p> <p>21 A. It was a piece of TVT, a few</p> <p>22 pieces of TVT put in formalin.</p> <p>23 <b>Q. When you say you put it in</b></p> <p>24 <b>formalin, did you do anything other than just put</b></p> <p>25 <b>it in a jar?</b></p>	<p style="text-align: right;">Page 32</p> <p>1 <b>Q. Okay. Tell me what that</b></p> <p>2 <b>experiment does?</b></p> <p>3 A. I did the same thing as I did for</p> <p>4 formalin exposure. I took pieces of mesh and put</p> <p>5 them in solutions of hydrogen peroxide, hydrogen</p> <p>6 peroxide with catalysts, few strong acids,</p> <p>7 solvents, and just they are stored in these</p> <p>8 solutions.</p> <p>9 <b>Q. How many pieces of mesh are you</b></p> <p>10 <b>testing?</b></p> <p>11 A. It's hard to say now. It might be</p> <p>12 over 20 small pieces.</p> <p>13 <b>Q. And how are they stored right now?</b></p> <p>14 A. In a dark room in a cabinet.</p> <p>15 <b>Q. In a vial?</b></p> <p>16 A. What do you mean, vial?</p> <p>17 <b>Q. Are they in a container with a</b></p> <p>18 <b>cover on them?</b></p> <p>19 A. Yes, of course. Some of them are</p> <p>20 acids and they're in glass containers.</p> <p>21 <b>Q. What temperature are they being</b></p> <p>22 <b>stored?</b></p> <p>23 A. Just room temperature.</p> <p>24 <b>Q. Do you have a protocol that you</b></p> <p>25 <b>wrote up for this test?</b></p>
<p style="text-align: right;">Page 31</p> <p>1 A. They were kept in formalin, in a</p> <p>2 jar, and then they were put in the cassette for</p> <p>3 tissue processing and then they went through the</p> <p>4 whole process of xylene alcohol and everything else</p> <p>5 and then I had slides made.</p> <p>6 <b>Q. And no analytical chemistry done</b></p> <p>7 <b>of that control, correct?</b></p> <p>8 A. Why would I? I'm doing histology.</p> <p>9 <b>Q. I understand. No analytical</b></p> <p>10 <b>chemistry; is that correct?</b></p> <p>11 A. That is correct.</p> <p>12 <b>Q. Thank you. Number 19.</b></p> <p>13 A. Yes.</p> <p>14 <b>Q. "Request all materials related</b></p> <p>15 <b>to testing of intentionally oxidized</b></p> <p>16 <b>polypropylene that had not been</b></p> <p>17 <b>implanted or exposed to formalin."</b></p> <p>18 <b>Do you see that?</b></p> <p>19 A. Yes, I do.</p> <p>20 <b>Q. Is there any information on</b></p> <p>21 <b>Exhibit No. 4 related to that kind of testing?</b></p> <p>22 A. No, because the test is still in</p> <p>23 progress. I mean, I kept part of mesh in different</p> <p>24 solutions and I haven't taken them out yet. I</p> <p>25 haven't examined them yet.</p>	<p style="text-align: right;">Page 33</p> <p>1 A. No. The only protocol I used was</p> <p>2 there was a published paper, they introduced this</p> <p>3 stimulated body environment -- simulated, not</p> <p>4 stimulated. Simulated body environment. Hydrogen</p> <p>5 peroxide was the catalyst. Catalyst is a chromium</p> <p>6 salt.</p> <p>7 <b>Q. Cobalt chloride?</b></p> <p>8 A. Probably.</p> <p>9 <b>Q. That's Dr. Guelcher's paper?</b></p> <p>10 A. I'm not sure if it's his paper,</p> <p>11 it's another paper. But anyway, I'm testing his</p> <p>12 protocol. I followed exactly the description in</p> <p>13 the paper and kept it in the solution for almost a</p> <p>14 year by now, but it's still too early to take it</p> <p>15 out.</p> <p>16 <b>Q. Why is it still too early to take</b></p> <p>17 <b>it out?</b></p> <p>18 A. Because based on my analysis of</p> <p>19 the specimens explanted from the body I can barely</p> <p>20 see the degradation bark after a year in the body.</p> <p>21 So if I take them now it would be too early.</p> <p>22 I may just waste samples, so I have to</p> <p>23 wait for probably a few extra months or maybe</p> <p>24 another year. Because by year two or 1 1/2 years</p> <p>25 in the body, the bark becomes visible in</p>



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<p>1 100 percent of the cases.</p> <p>2 If I take them out by 12 months, I may</p> <p>3 or may not see something and then it would -- I'll</p> <p>4 just waste samples.</p> <p>5 <b>Q. Did you prepare the solution in</b></p> <p>6 <b>which these samples are stored?</b></p> <p>7 A. Yes, I did.</p> <p>8 <b>Q. And what is the recipe for the</b></p> <p>9 <b>solution that you used?</b></p> <p>10 A. It's written in the original paper</p> <p>11 I used for the --</p> <p>12 <b>Q. Can you tell me what the original</b></p> <p>13 <b>paper is?</b></p> <p>14 A. I'd have to check now.</p> <p>15 <b>Q. And how many samples are stored?</b></p> <p>16 A. As I said, probably over 20.</p> <p>17 <b>Q. And how many different kinds of</b></p> <p>18 <b>mesh are being tested?</b></p> <p>19 A. There is one from one</p> <p>20 manufacturer, and then -- four types of mesh.</p> <p>21 <b>Q. How many Ethicon meshes are being</b></p> <p>22 <b>tested?</b></p> <p>23 A. At least one.</p> <p>24 <b>Q. What kind?</b></p> <p>25 A. It's written on the jars. I may</p>	<p>1 A. At least four different type of</p> <p>2 mesh. I would have to check with the labels what</p> <p>3 is written there, what manufacturers, what mesh was</p> <p>4 put in there. I don't remember. It's been a year.</p> <p>5 <b>Q. Are you working with anybody else</b></p> <p>6 <b>on that experiment?</b></p> <p>7 A. No.</p> <p>8 <b>Q. This is solely your work?</b></p> <p>9 A. Yes.</p> <p>10 <b>Q. Did you consult with anybody about</b></p> <p>11 <b>the kind of solution that you would use for your</b></p> <p>12 <b>experiment?</b></p> <p>13 A. No. Whom I would consult? Nobody</p> <p>14 did it before. The only information I extracted</p> <p>15 was from that specific simulation body environment</p> <p>16 simulation from the paper.</p> <p>17 <b>Q. You know Dr. Guelcher has tried to</b></p> <p>18 <b>insulate oxidized polypropylene, don't you?</b></p> <p>19 MR. ORENT: Objection.</p> <p>20 THE WITNESS: I know that he did an</p> <p>21 experiment, and he asked me what I see. I said</p> <p>22 it's too early, I'm not going to take them out yet.</p> <p>23 I will keep them a little longer.</p> <p>24 BY MR. THOMAS:</p> <p>25 <b>Q. Did Dr. Guelcher tell you he had</b></p>
Page 35	Page 37
<p>1 have to check later.</p> <p>2 <b>Q. Doctor, do you have an inventory</b></p> <p>3 <b>of what's in each vial written down?</b></p> <p>4 A. It's written on the jar.</p> <p>5 <b>Q. Is it written down on a piece of</b></p> <p>6 <b>paper anywhere?</b></p> <p>7 A. No.</p> <p>8 MR. ORENT: Objection.</p> <p>9 BY MR. THOMAS:</p> <p>10 <b>Q. Is it written in a computer</b></p> <p>11 <b>somewhere?</b></p> <p>12 A. No, just on jars. Jars label when</p> <p>13 the case was put and what type of mesh was put in.</p> <p>14 <b>Q. When did you start this</b></p> <p>15 <b>experiment?</b></p> <p>16 A. Last September.</p> <p>17 <b>Q. So it's been a full year?</b></p> <p>18 A. Yes.</p> <p>19 <b>Q. And did you put the mesh in this</b></p> <p>20 <b>solution in these 20 or so samples all at the same</b></p> <p>21 <b>time?</b></p> <p>22 A. Within two weeks.</p> <p>23 <b>Q. All right. As I understand it,</b></p> <p>24 <b>there are at least four different mesh</b></p> <p>25 <b>manufacturers that are a part of this experiment?</b></p>	<p>1 <b>intentionally oxidized polypropylene by exposing it</b></p> <p>2 <b>to some chemical solution?</b></p> <p>3 MR. ORENT: Objection.</p> <p>4 THE WITNESS: Yes, he did.</p> <p>5 BY MR. THOMAS:</p> <p>6 <b>Q. Did you ask him to have that mesh</b></p> <p>7 <b>so that you could determine whether this</b></p> <p>8 <b>intentionally oxidized polypropylene absorbed</b></p> <p>9 <b>stain?</b></p> <p>10 MR. ORENT: Objection.</p> <p>11 THE WITNESS: No.</p> <p>12 BY MR. THOMAS:</p> <p>13 <b>Q. Why not?</b></p> <p>14 MR. ORENT: Objection.</p> <p>15 THE WITNESS: Because I'm doing my own</p> <p>16 experiment and I believe I need to keep it for at</p> <p>17 least a year and a half.</p> <p>18 BY MR. THOMAS:</p> <p>19 <b>Q. Did you discuss with Dr. Guelcher</b></p> <p>20 <b>the scope of his experiment?</b></p> <p>21 MR. ORENT: Objection. At this point,</p> <p>22 Counsel, I think you're getting into -- I think you</p> <p>23 need to clarify whether your questions are in the</p> <p>24 context of litigation or research.</p> <p>25 To the extent it's in litigation it's</p>

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<p style="text-align: right;">Page 38</p> <p>1 covered by privilege and I would instruct the</p> <p>2 witness not to answer under the rules. But to the</p> <p>3 extent that you're discussing research, I think</p> <p>4 that's fair game to discuss.</p> <p>5 BY MR. THOMAS:</p> <p>6 <b>Q. Okay. From a research</b></p> <p>7 <b>perspective, did you have any discussions with Dr.</b></p> <p>8 <b>Guelcher about his experiment?</b></p> <p>9 A. It's work in progress so it's</p> <p>10 privileged to researchers, I guess, at this point.</p> <p>11 <b>Q. Are you going to assert a</b></p> <p>12 <b>privilege for your research?</b></p> <p>13 A. For research information, yes.</p> <p>14 <b>Q. Okay. And you asserted a</b></p> <p>15 <b>litigation privilege, which I don't think is</b></p> <p>16 <b>appropriate -- I'm not arguing with you. You said</b></p> <p>17 <b>there's no research privilege. Now he's trying to</b></p> <p>18 <b>assert a research privilege?</b></p> <p>19 MR. ORENT: No, what I said was in</p> <p>20 terms of legal -- in terms of legal privileges that</p> <p>21 I can, that I have, that I have an attorney-client --</p> <p>22 excuse me, a attorney work product under the Rule</p> <p>23 26.</p> <p>24 Rule 26 specifically allows for expert</p> <p>25 witnesses to consult with one another under the</p>	<p style="text-align: right;">Page 40</p> <p>1 this.</p> <p>2 MR. THOMAS: Thank you.</p> <p>3 -- RECESS AT 9:42 --</p> <p>4 -- UPON RESUMING AT 9:43 --</p> <p>5 MR. ORENT: We can go back on the</p> <p>6 record.</p> <p>7 I'll just say for the record over the</p> <p>8 break I just explained to Dr. Iakovlev what the</p> <p>9 highly confidential designation is and that all the</p> <p>10 lawyers in this litigation have all signed on to</p> <p>11 it.</p> <p>12 Confidentiality agreement whereby there</p> <p>13 are limited distribution on each side as to who can</p> <p>14 receive highly confidential information and that</p> <p>15 after discussing it I believe the witness is</p> <p>16 comfortable with the designation and will proceed</p> <p>17 to answer.</p> <p>18 BY MR. THOMAS:</p> <p>19 <b>Q. Thank you. Have you have</b></p> <p>20 <b>discussed with Dr. Guelcher the results of his</b></p> <p>21 <b>test?</b></p> <p>22 A. Yes, I asked him what he saw.</p> <p>23 <b>Q. And what did he tell you?</b></p> <p>24 A. He said that there is flaking on</p> <p>25 the surface early, it's not confluent but there are</p>
<p style="text-align: right;">Page 39</p> <p>1 2010 amendments to the federal rules.</p> <p>2 So, what I was clarifying is that it is</p> <p>3 my privilege to seek and to utilize for my client,</p> <p>4 and that's what I was exercising with regard to</p> <p>5 non-research thought processes for litigation.</p> <p>6 To the extent Dr. Iakovlev has</p> <p>7 proprietary interests in research that is ongoing</p> <p>8 or may be ongoing, that's up to him as to whether</p> <p>9 or not -- and I know that on both sides in this</p> <p>10 mesh litigation have previously taken a position</p> <p>11 that those sort of things are not discoverable.</p> <p>12 To the extent the doctor is</p> <p>13 comfortable, I'd be happy to designate this portion</p> <p>14 of the transcript highly confidential and allow the</p> <p>15 witness to answer.</p> <p>16 THE WITNESS: I also need to add that</p> <p>17 that experiment is not in my opinions. I was not</p> <p>18 base my opinions on any part of that experiment.</p> <p>19 And I'm not really sure why you asking me these</p> <p>20 questions.</p> <p>21 BY MR. THOMAS:</p> <p>22 <b>Q. Because I get to ask them.</b></p> <p>23 MR. ORENT: If I can just have a minute</p> <p>24 with the witness and explain what the highly</p> <p>25 confidential designation means, that may clarify</p>	<p style="text-align: right;">Page 41</p> <p>1 some flakes forming.</p> <p>2 I said it might be too early, because</p> <p>3 he did it I think on six weeks or so, maybe more,</p> <p>4 maybe up to three months.</p> <p>5 I said, well, I keep my specimens for</p> <p>6 at least a year and a half because I believe that</p> <p>7 that's much time you need to make it visible by my</p> <p>8 techniques. Maybe by SCM we can see a little bit</p> <p>9 earlier, and we stopped at that.</p> <p>10 <b>Q. Do you know whether he conducted</b></p> <p>11 <b>any analytical chemistry testing on any of the mesh</b></p> <p>12 <b>he analyzed?</b></p> <p>13 A. I think he did.</p> <p>14 MR. ORENT: Objection.</p> <p>15 THE WITNESS: I don't remember at this</p> <p>16 point. It's not my specifically methodology, so I</p> <p>17 didn't do these things.</p> <p>18 BY MR. THOMAS:</p> <p>19 <b>Q. Did you have discussions with Dr.</b></p> <p>20 <b>Guelcher about trying to stain the polypropylene</b></p> <p>21 <b>that he had intentionally oxidized?</b></p> <p>22 A. He asked me. I said it's too</p> <p>23 early.</p> <p>24 <b>Q. Okay?</b></p> <p>25 A. So I said maybe by your methods</p>

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<p style="text-align: right;">Page 42</p> <p>1 you can detect it. By my methods, probably I</p> <p>2 cannot. And I said I will keep my pieces for</p> <p>3 longer and then we'll see what happens.</p> <p>4 <b>Q. And how did you decide -- strike</b></p> <p>5 <b>that. Did I understand you to say that you have</b></p> <p>6 <b>chosen 18 months as the time when you think it will</b></p> <p>7 <b>be appropriate to test for oxidation?</b></p> <p>8 MR. ORENT: Objection to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. THOMAS:</p> <p>11 <b>Q. And at 18 months is it your</b></p> <p>12 <b>intention to remove all of those meshes from the</b></p> <p>13 <b>chemical solution and determine whether it's</b></p> <p>14 <b>intentionally oxidized?</b></p> <p>15 A. Part of it. Probably not all of</p> <p>16 them in one shot. I will start taking some pieces</p> <p>17 and examining them see what happens and if I --</p> <p>18 depends on what I see, I may keep them longer.</p> <p>19 <b>Q. And what kind of tests do you</b></p> <p>20 <b>propose to run on them after 18 months?</b></p> <p>21 A. Histology, what I've done -- what</p> <p>22 I showed in the paper.</p> <p>23 <b>Q. The same kind of tests that you've</b></p> <p>24 <b>run on the meshes that are contained in your</b></p> <p>25 <b>reports?</b></p>	<p style="text-align: right;">Page 44</p> <p>1 A. They came from some law firms</p> <p>2 during earlier cases.</p> <p>3 <b>Q. Okay. And where did you get the</b></p> <p>4 <b>chemicals?</b></p> <p>5 A. I said, they are in the lab.</p> <p>6 <b>Q. Okay. So you used materials from</b></p> <p>7 <b>the St. Michael's histo lab to put them, and you</b></p> <p>8 <b>combined those chemicals in a recipe that you're</b></p> <p>9 <b>now exposing this polypropylene to?</b></p> <p>10 A. That is correct. These are</p> <p>11 regular chemicals that are used in histo lab.</p> <p>12 <b>Q. And the reason why you're doing</b></p> <p>13 <b>this test is to determine whether, first, after</b></p> <p>14 <b>18 months this polypropylene will oxidize due to</b></p> <p>15 <b>exposure to this chemical mixture, correct?</b></p> <p>16 A. Could you repeat the question?</p> <p>17 MR. THOMAS: Can you read it back?</p> <p>18 -- REPORTER'S NOTE: Question read back</p> <p>19 as recorded above.</p> <p>20 THE WITNESS: That's correct.</p> <p>21 BY MR. THOMAS:</p> <p>22 <b>Q. And how will you determine whether</b></p> <p>23 <b>it's oxidized?</b></p> <p>24 A. I would see degradation layer on</p> <p>25 the surface.</p>
<p style="text-align: right;">Page 43</p> <p>1 A. Similar.</p> <p>2 <b>Q. Any differences?</b></p> <p>3 A. Don't plan on anything different</p> <p>4 at this point. I may, I mean, it's work in</p> <p>5 progress research. Maybe I'll find something else,</p> <p>6 I don't know.</p> <p>7 <b>Q. Are you consulting with anybody</b></p> <p>8 <b>else on this particular experiment?</b></p> <p>9 A. We discussed it only with Scott</p> <p>10 Guelcher.</p> <p>11 <b>Q. And is the mesh that's being</b></p> <p>12 <b>tested pristine new mesh?</b></p> <p>13 A. Yes.</p> <p>14 <b>Q. Never been exposed to tissue?</b></p> <p>15 A. That is correct.</p> <p>16 <b>Q. Never been exposed to formalin?</b></p> <p>17 A. That is correct.</p> <p>18 <b>Q. Who is paying for this testing?</b></p> <p>19 A. Nobody. I just took chemicals</p> <p>20 from our histo lab.</p> <p>21 <b>Q. Did counsel fund this experiment?</b></p> <p>22 A. No, there is no additional</p> <p>23 funding. What funding would I need for it?</p> <p>24 Chemicals are in the lab.</p> <p>25 <b>Q. Where did you get the mesh?</b></p>	<p style="text-align: right;">Page 45</p> <p>1 <b>Q. And that would be by light</b></p> <p>2 <b>microscopy?</b></p> <p>3 A. Yes.</p> <p>4 MR. ORENT: Objection.</p> <p>5 BY MR. THOMAS:</p> <p>6 <b>Q. Any other analytical technique</b></p> <p>7 <b>that you propose to use?</b></p> <p>8 A. As I said, none at this point.</p> <p>9 <b>Q. And as a part of your experiment</b></p> <p>10 <b>do you then intend to see whether -- if you are</b></p> <p>11 <b>able to oxidize polypropylene, according to your</b></p> <p>12 <b>visual observation by light microscopy, will you</b></p> <p>13 <b>then see whether the oxidized polypropylene holds</b></p> <p>14 <b>stain?</b></p> <p>15 A. Yes, that's the way to see it.</p> <p>16 This just becomes porous and after absorbs stain.</p> <p>17 <b>Q. And the way you will test that is</b></p> <p>18 <b>the same way you've processed the slides in Exhibit</b></p> <p>19 <b>No. 1 and 2 -- you'll put them through the sample</b></p> <p>20 <b>preparation histology analysis that you've done in</b></p> <p>21 <b>all your other cases?</b></p> <p>22 A. Can be tried without putting them</p> <p>23 through histology; you can immerse exposed mesh</p> <p>24 into the dye solution.</p> <p>25 <b>Q. Just drop it in the jar?</b></p>

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<p style="text-align: right;">Page 46</p> <p>1 A. Pretty much. If it stains, then</p> <p>2 you can see staining on the surface. That means</p> <p>3 there is a layer of porous polypropylene on the</p> <p>4 surface.</p> <p>5 It's like, this is not stain, this is</p> <p>6 anodized aluminum. So there's porous layer on</p> <p>7 aluminum. If you drop unprepared aluminum in the</p> <p>8 jar with black ink it will not absorb anything</p> <p>9 because it's sealed.</p> <p>10 If you drop it with anodized layer it</p> <p>11 will become black because it will absorb it. It's</p> <p>12 the same technique; it's pretty basic.</p> <p>13 <b>Q. I understand. Thank you.</b></p> <p>14 <b>Are you aware of a method where you can</b></p> <p>15 <b>take a piece of pristine mesh that's been exposed</b></p> <p>16 <b>as you've described, and prepare a histological</b></p> <p>17 <b>slide of that exposed material without embedding it</b></p> <p>18 <b>in some other medium?</b></p> <p>19 A. Let me ask you if I got your</p> <p>20 question right.</p> <p>21 Am I aware of a histological technique</p> <p>22 which will allow me to cut through the mesh without</p> <p>23 embedding it into anything?</p> <p>24 <b>Q. Correct.</b></p> <p>25 A. No. It has to be embedded into</p>	<p style="text-align: right;">Page 48</p> <p>1 <b>A and B, identified as Figure Set 16 A, is</b></p> <p>2 <b>identified as "cracking on the surface of TVT mesh</b></p> <p>3 <b>fibers immediately after removal from the body".</b></p> <p>4 <b>Where did you get this?</b></p> <p>5 A. This was a St. Michael's patient.</p> <p>6 So when it was excised I immediately placed it</p> <p>7 under the microscope.</p> <p>8 <b>Q. How did you know it was being</b></p> <p>9 <b>excised?</b></p> <p>10 A. What do you mean how do I know?</p> <p>11 We receive specimens.</p> <p>12 <b>Q. Just so I understand -- strike</b></p> <p>13 <b>that.</b></p> <p>14 <b>Typically after a surgical procedure</b></p> <p>15 <b>when mesh is excised the surgeon immediately places</b></p> <p>16 <b>it in formalin, correct?</b></p> <p>17 A. Not always.</p> <p>18 <b>Q. Okay.</b></p> <p>19 A. We receive it fresh, so in this</p> <p>20 case it was fresh.</p> <p>21 <b>Q. And did you discuss with the</b></p> <p>22 <b>surgeon any of the circumstances of removal?</b></p> <p>23 A. This was a St. Michael's specimen,</p> <p>24 so I did ask, but I'm not sure if I can go there</p> <p>25 because of the confidentiality issues. It was not</p>
<p style="text-align: right;">Page 47</p> <p>1 some form of medium to hold it for the knife to cut</p> <p>2 through.</p> <p>3 <b>Q. Have you devised or thought of a</b></p> <p>4 <b>method to do that?</b></p> <p>5 A. No. Why would I?</p> <p>6 <b>Q. If you're going to do a histology</b></p> <p>7 <b>slide of this mesh that's been exposed to chemicals</b></p> <p>8 <b>after a year and a half, you're going to have to</b></p> <p>9 <b>put it in some medium before the microtome can cut</b></p> <p>10 <b>it, correct?</b></p> <p>11 A. Paraffin.</p> <p>12 <b>Q. So you're going to put the mesh by</b></p> <p>13 <b>itself in paraffin and cut it from there?</b></p> <p>14 A. Yes.</p> <p>15 <b>Q. Okay.</b></p> <p>16 A. That's how it's done.</p> <p>17 <b>Q. That's fine. Doctor, on page 82</b></p> <p>18 <b>of your report?</b></p> <p>19 A. Yes.</p> <p>20 <b>Q. Are you on page 82? That's where</b></p> <p>21 <b>I want you to be.</b></p> <p>22 A. Oh, yes, okay.</p> <p>23 <b>Q. I'm sorry, 83. I apologize, I was</b></p> <p>24 <b>wrong.</b></p> <p>25 <b>Page 83 of your report has two images,</b></p>	<p style="text-align: right;">Page 49</p> <p>1 a medical-legal case.</p> <p>2 <b>Q. Who was the doctor that you</b></p> <p>3 <b>discussed it with?</b></p> <p>4 A. I don't know if I can disclose it.</p> <p>5 <b>Q. I'm going to ask you to and if you</b></p> <p>6 <b>tell me no, you tell me no?</b></p> <p>7 A. Again, I'm not sure if I can</p> <p>8 disclose that because it is confidential</p> <p>9 information.</p> <p>10 <b>Q. Are you telling me you're not</b></p> <p>11 <b>going to? That's fine. Tell me you're not going</b></p> <p>12 <b>to and I'll move on.</b></p> <p>13 A. No, I will not. I will not</p> <p>14 because I don't want to compromise confidentiality.</p> <p>15 <b>Q. Okay. Can you tell me the nature</b></p> <p>16 <b>of the conversation you had with this doctor?</b></p> <p>17 A. Oh, I asked her later on what was</p> <p>18 -- because then I would ask how long it's been in</p> <p>19 the body, some information was on the records and</p> <p>20 just basic information.</p> <p>21 <b>Q. Did you get medical records for</b></p> <p>22 <b>this mesh?</b></p> <p>23 A. It was in medical -- in the</p> <p>24 medical records of St. Michael's Hospital.</p> <p>25 <b>Q. Did you produce on the thumb</b></p>

13 (Pages 46 to 49)

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<p style="text-align: right;">Page 50</p> <p>1 <b>drive, Exhibit No. 4, the medical records for the</b>  2 <b>patient that's on page 83?</b>  3 MR. ORENT: Objection.  4 THE WITNESS: No, it's confidential  5 information, St. Michael's Hospital information.  6 And the picture is not coming from a case itself;  7 picture is coming from a publication.  8 BY MR. THOMAS:  9 <b>Q. Well, it's your publication; is</b>  10 <b>that fair?</b>  11 A. Yes.  12 MR. ORENT: Objection.  13 BY MR. THOMAS:  14 <b>Q. Okay?</b>  15 A. But it's not coming from a set of  16 TVT or TVT-O cases which are received within the  17 litigation process. It's coming from a publication  18 and for that publication I had REB approval and  19 there are strict rules what can be disclosed, what  20 cannot be disclosed.  21 <b>Q. How long from the removal of this</b>  22 <b>mesh until the time you looked under the</b>  23 <b>microscope?</b>  24 A. I would say an hour, maybe  25 40 minutes, maybe less.</p>	<p style="text-align: right;">Page 52</p> <p>1 Not only specifically for this case, I  2 asked if you can sometimes help me with what you're  3 excising, or submit it in saline, so it's not  4 exposed to formalin because I needed samples to be  5 put in a glutaraldehyde. This came in saline.  6 BY MR. THOMAS:  7 <b>Q. Was this put in glutaraldehyde</b>  8 <b>before you made this image?</b>  9 A. No, it was put in saline. I  10 received it in saline, I examined it, took pictures  11 and put it in formalin.  12 <b>Q. Other than putting it in saline,</b>  13 <b>was any effort made to clean the mesh prior to the</b>  14 <b>time that you took these images?</b>  15 A. No, just washed them in saline,  16 that's it.  17 <b>Q. Was it washed in saline or just</b>  18 <b>soaked in saline?</b>  19 A. What's the difference?  20 <b>Q. Well, there was no effort to wash</b>  21 <b>it, it was merely stored in saline before you took</b>  22 <b>your images; is that fair?</b>  23 A. You immerse something in fluid;  24 it's being washed.  25 <b>Q. Okay. Go to page 5 of your</b></p>
<p style="text-align: right;">Page 51</p> <p>1 <b>Q. How did you manage to get it so</b>  2 <b>quickly?</b>  3 A. We have a lab in the OR. OR is  4 practically -- I mean, our receiving area for  5 specimens is in OR, it's like there.  6 <b>Q. Did you tell the doctor if she</b>  7 <b>ever got a TVT specimen that you'd like to have it</b>  8 <b>before it was put in formalin?</b>  9 A. No, but I told, I told several  10 physicians and several -- everybody knows that I'm  11 working on meshes, so people know that I'm  12 interested in meshes.  13 <b>Q. My question was, did you tell a</b>  14 <b>doctor to give one to you before it was exposed to</b>  15 <b>formalin?</b>  16 MR. ORENT: Objection. Can I just ask  17 for clarification. Your prior question was --  18 included the word TVT. Prior testimony on this was  19 that this was not a TVT, I believe. Oh, this is a  20 TVT, I apologize.  21 THE WITNESS: In the earlier, very  22 early when we started working on these meshes, the  23 question was how do I process them for scanning of  24 -- transmission of electron microscopy, and I  25 needed fresh samples.</p>	<p style="text-align: right;">Page 53</p> <p>1 <b>report, please.</b>  2 A. Yes.  3 <b>Q. Down at the bottom of the page,</b>  4 <b>the sentence, it reads:</b>  5 <b>"Immediately after placement in</b>  6 <b>the body, foreign objects become</b>  7 <b>coated with human proteins before</b>  8 <b>appearance of the inflammatory</b>  9 <b>cells."</b>  10 <b>Do you see that?</b>  11 A. Yes.  12 <b>Q. What does that mean?</b>  13 A. It means that anything you put in  14 the body will get coated by serum proteins.  15 <b>Q. How many different kinds of</b>  16 <b>proteins are there in the body?</b>  17 A. Very large number, thousands,  18 maybe millions.  19 <b>Q. Is there a special kind of protein</b>  20 <b>that surrounds the foreign body?</b>  21 A. It's non-specific. The area will  22 be filled with blood immediately, so main proteins  23 are in the serum, so it will be albumin, some  24 immunoglobins, then the blood clotting cascade sets  25 in.</p>

14 (Pages 50 to 53)

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<p style="text-align: right;">Page 54</p> <p>1 So there will be more of a fibrinogen</p> <p>2 and fibrin, all of those proteins which are</p> <p>3 involved in blood clotting. It depends what</p> <p>4 timeframe we're talking about, immediate coating,</p> <p>5 or minutes or hours or days after.</p> <p>6 <b>Q. Do you know what protein</b></p> <p>7 <b>adsorption is, A-D-S-O-R-P-T-I-O-N?</b></p> <p>8 A. You mean adherence of the protein</p> <p>9 to the surface?</p> <p>10 <b>Q. Are you familiar with that?</b></p> <p>11 A. I mean, that's the term as I</p> <p>12 understand it.</p> <p>13 <b>Q. Do you know chemically how that</b></p> <p>14 <b>works?</b></p> <p>15 A. For all proteins?</p> <p>16 <b>Q. For protein adsorption to foreign</b></p> <p>17 <b>bodies; do you know how it works?</b></p> <p>18 A. Not the specific chemical details.</p> <p>19 <b>Q. Do you know the extent to which</b></p> <p>20 <b>the proteins form a bond with the foreign body?</b></p> <p>21 A. Not the specific details.</p> <p>22 <b>Q. Do you specifically with</b></p> <p>23 <b>polypropylene – or strike that. Specifically with</b></p> <p>24 <b>Prolene, do you have any information about the</b></p> <p>25 <b>extent to which human proteins form a bond with the</b></p>	<p style="text-align: right;">Page 56</p> <p>1 <b>analyzed as groups?</b></p> <p>2 A. Which page number?</p> <p>3 <b>Q. I'm on 82.</b></p> <p>4 A. Okay.</p> <p>5 <b>Q. 82 is called, "Figure Set 15, TVT</b></p> <p>6 <b>Meshes Analyzed as a Group".</b></p> <p>7 <b>And you're doing a statistical analysis</b></p> <p>8 <b>here of the TVT meshes; is that correct?</b></p> <p>9 A. That's correct.</p> <p>10 <b>Q. Are the TVT meshes described on</b></p> <p>11 <b>page 82 the meshes that you got from Dr. Kreutzer?</b></p> <p>12 A. Some of them.</p> <p>13 <b>Q. How many of them?</b></p> <p>14 A. I don't remember now. Probably</p> <p>15 about 20 or 19.</p> <p>16 <b>Q. And how many are in this group?</b></p> <p>17 A. 23.</p> <p>18 <b>Q. So probably 19 or 20 out of 23</b></p> <p>19 <b>were meshes you got from Dr. Kreutzer?</b></p> <p>20 A. Probably, but I'm not sure. I</p> <p>21 don't remember now.</p> <p>22 <b>Q. Are you a trained statistician?</b></p> <p>23 A. No, but I had my statistics when I</p> <p>24 did my research training.</p> <p>25 <b>Q. Okay. Who chose the statistical</b></p>
<p style="text-align: right;">Page 55</p> <p>1 <b>Prolene polypropylene?</b></p> <p>2 MR. ORENT: Objection.</p> <p>3 THE WITNESS: No.</p> <p>4 BY MR. THOMAS:</p> <p>5 <b>Q. Do you have any information about</b></p> <p>6 <b>the extent to which saline is adequate to remove</b></p> <p>7 <b>any proteins that are adsorbed on to the Prolene</b></p> <p>8 <b>mesh?</b></p> <p>9 A. No, I think it's irrelevant</p> <p>10 because that mesh which was examined didn't have</p> <p>11 time to dry and couldn't dry because it was in</p> <p>12 saline.</p> <p>13 So if it cracks it means that it had</p> <p>14 time to crack. In this case it couldn't dry.</p> <p>15 <b>Q. There's no analytical chemistry</b></p> <p>16 <b>done on this, correct?</b></p> <p>17 A. No.</p> <p>18 <b>Q. There are none; am I correct?</b></p> <p>19 A. You are correct.</p> <p>20 <b>Q. Thank you. So, you're basing your</b></p> <p>21 <b>opinion on the cracking, which you claim to be the</b></p> <p>22 <b>Prolene, based on your visual observation?</b></p> <p>23 A. That is correct.</p> <p>24 <b>Q. Let's go back to page 82, please</b></p> <p>25 <b>which is your statistical analysis of TVT meshes</b></p>	<p style="text-align: right;">Page 57</p> <p>1 <b>method that's employed here?</b></p> <p>2 A. I did.</p> <p>3 <b>Q. And why?</b></p> <p>4 A. What do you mean why?</p> <p>5 <b>Q. Why was this method the method you</b></p> <p>6 <b>chose?</b></p> <p>7 A. Because it's the method to check</p> <p>8 what I was intending to check.</p> <p>9 <b>Q. And tell me why that is an</b></p> <p>10 <b>appropriate method for what you have done?</b></p> <p>11 A. What do you mean?</p> <p>12 <b>Q. Why is this Pearson coefficient?</b></p> <p>13 A. Pearson coefficient? It's a</p> <p>14 standard correlation coefficient method.</p> <p>15 <b>Q. Are you aware of other statistical</b></p> <p>16 <b>methods to test your results?</b></p> <p>17 A. What do you mean? For</p> <p>18 correlation?</p> <p>19 <b>Q. Yes.</b></p> <p>20 A. Could be Spearman.</p> <p>21 <b>Q. Spearman?</b></p> <p>22 A. Yes.</p> <p>23 <b>Q. Any others, R-squared?</b></p> <p>24 A. For correlation?</p> <p>25 <b>Q. Yes.</b></p>

15 (Pages 54 to 57)

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<p style="text-align: right;">Page 58</p> <p>1 A. There might be others, but the</p> <p>2 main are Pearson and Spearman; there is not much</p> <p>3 difference between them.</p> <p>4 <b>Q. Is the raw data you used to do</b></p> <p>5 <b>your statistical correlation on Exhibit 4?</b></p> <p>6 A. Yes, it is.</p> <p>7 <b>Q. And how is it marked, so if I</b></p> <p>8 <b>wanted to find it, I could see it?</b></p> <p>9 A. It's in a separate file it's</p> <p>10 called 23 TVT-O and something else for the chart.</p> <p>11 <b>Q. So if I wanted to have a</b></p> <p>12 <b>statistician run a different model, all of the data</b></p> <p>13 <b>he would need to do it is on Exhibit 4?</b></p> <p>14 A. Yes. It's there.</p> <p>15 <b>Q. Okay. Doctor, since you were last</b></p> <p>16 <b>deposed, you've had a couple of studies published</b></p> <p>17 <b>in journals?</b></p> <p>18 A. Probably more than a couple, yes,</p> <p>19 I did.</p> <p>20 <b>Q. And your deposition notice</b></p> <p>21 <b>requested communications with the journals about</b></p> <p>22 <b>publications that you produced. Are those on</b></p> <p>23 <b>Exhibit 4?</b></p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: I believe it's</p>	<p style="text-align: right;">Page 60</p> <p>1 was quick answer, right away, that's not in our</p> <p>2 scope.</p> <p>3 <b>Q. So how many journals did not</b></p> <p>4 <b>accept your publication?</b></p> <p>5 MR. ORENT: Objection.</p> <p>6 THE WITNESS: I don't remember now.</p> <p>7 BY MR. THOMAS:</p> <p>8 <b>Q. Okay. Do you have that</b></p> <p>9 <b>information?</b></p> <p>10 A. Probably somewhere in the replies</p> <p>11 I can find it.</p> <p>12 <b>Q. Okay. Did you ever disclose to</b></p> <p>13 <b>the journals to which you submitted these</b></p> <p>14 <b>publications that some of the work contained in the</b></p> <p>15 <b>journal publication had been funded by plaintiff's</b></p> <p>16 <b>counsel?</b></p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: Nothing was funded by</p> <p>19 plaintiff's counsel. They were litigation cases</p> <p>20 but I didn't get any additional funding to conduct</p> <p>21 the study.</p> <p>22 BY MR. THOMAS:</p> <p>23 <b>Q. Certainly the slides from Dr.</b></p> <p>24 <b>Kreutzer were provided to you by plaintiff's</b></p> <p>25 <b>counsel?</b></p>
<p style="text-align: right;">Page 59</p> <p>1 confidential to me as a researcher, privileged.</p> <p>2 They've been published, they've been accepted, they</p> <p>3 are publicly available.</p> <p>4 BY MR. THOMAS:</p> <p>5 <b>Q. Is the answer to my question no,</b></p> <p>6 <b>you didn't produce any of those communications?</b></p> <p>7 A. No, I didn't.</p> <p>8 <b>Q. Do you have such communications?</b></p> <p>9 A. Acceptance letters, that's about</p> <p>10 it.</p> <p>11 <b>Q. Do you have any comments or</b></p> <p>12 <b>criticisms from any peer reviewers?</b></p> <p>13 MR. ORENT: Objection.</p> <p>14 THE WITNESS: There were some.</p> <p>15 BY MR. THOMAS:</p> <p>16 <b>Q. Do you still have those?</b></p> <p>17 A. Yes, I do.</p> <p>18 <b>Q. Were any of these articles</b></p> <p>19 <b>rejected by any journals?</b></p> <p>20 A. Sometimes I submit to one journal</p> <p>21 they say it's out of scope it's probably best</p> <p>22 suited for another journal so it bounces back.</p> <p>23 I don't remember specific rejection,</p> <p>24 saying that the data isn't reliable. The only way</p> <p>25 -- the only time when the paper was not accepted it</p>	<p style="text-align: right;">Page 61</p> <p>1 MR. ORENT: Objection, argumentative.</p> <p>2 THE WITNESS: I didn't use them.</p> <p>3 BY MR. THOMAS:</p> <p>4 <b>Q. In your study? Isn't that what --</b></p> <p>5 A. I meant I didn't use the stains he</p> <p>6 used. I re-stained on stain slides. Maybe even</p> <p>7 cut the blocks.</p> <p>8 <b>Q. So is it your testimony that all</b></p> <p>9 <b>of the information that you submitted to the</b></p> <p>10 <b>journals was unrelated to your medical-legal work?</b></p> <p>11 A. No. It's not unrelated because</p> <p>12 some samples came for medical-legal purposes.</p> <p>13 <b>Q. And for which you were paid to</b></p> <p>14 <b>analyze by plaintiff's counsel, correct?</b></p> <p>15 A. To provide reports.</p> <p>16 <b>Q. And what percentage of the cases</b></p> <p>17 <b>that you report in the study were cases for which</b></p> <p>18 <b>you were compensated by plaintiff's counsel?</b></p> <p>19 MR. ORENT: Objection.</p> <p>20 THE WITNESS: The study was not</p> <p>21 compensated by anyone. I did it on my own time,</p> <p>22 during my own time, and I don't know why you're</p> <p>23 saying that.</p> <p>24 The percentage of cases which came</p> <p>25 through medical-legal litigation process is</p>

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<p style="text-align: right;">Page 62</p> <p>1 indicated in the paper.</p> <p>2 BY MR. THOMAS:</p> <p>3 <b>Q. Okay. We'll get to that in a</b></p> <p>4 <b>minute.</b></p> <p>5 <b>In the last year you've traveled and</b></p> <p>6 <b>made presentations around the world on the research</b></p> <p>7 <b>that you've done?</b></p> <p>8 A. Yes, I did.</p> <p>9 <b>Q. Who has funded that work?</b></p> <p>10 A. Pretty much I did.</p> <p>11 <b>Q. Did anybody subsidize your trips?</b></p> <p>12 A. No, I mean, we have a specific</p> <p>13 portion of our salary from St. Michael's Hospital</p> <p>14 which is dedicated for presentations. But it's</p> <p>15 within my salary, it's more or less a way of</p> <p>16 getting it through a different tax bracket because</p> <p>17 it's money spent for -- it's within my contract.</p> <p>18 <b>Q. Did you receive any funds from</b></p> <p>19 <b>plaintiff's counsel for your presentations in the</b></p> <p>20 <b>last year?</b></p> <p>21 A. Never.</p> <p>22 <b>Q. The articles that you had worked</b></p> <p>23 <b>on --</b></p> <p>24 A. The full answer would be I paid</p> <p>25 for all the trips and I never received any money</p>	<p style="text-align: right;">Page 64</p> <p>1 because it was in a publication.</p> <p>2 <b>Q. Did you obtain permission from the</b></p> <p>3 <b>patient to do that?</b></p> <p>4 A. For using the -- we have a</p> <p>5 standard protocol for research. We use material</p> <p>6 for research purpose and I had REB approval.</p> <p>7 <b>Q. Did you obtain permission from the</b></p> <p>8 <b>patient to use this image?</b></p> <p>9 A. As I said, each person who enters</p> <p>10 the hospital, academic hospital, St. Michael's</p> <p>11 Hospital, signs agreements or release form and it's</p> <p>12 covered by blanket research regulations.</p> <p>13 <b>Q. Does the patient know that her</b></p> <p>14 <b>mesh fiber was featured in a publication?</b></p> <p>15 A. No, I didn't tell her specifically</p> <p>16 to the patient.</p> <p>17 <b>Q. Okay. So the entirety of the</b></p> <p>18 <b>excised mesh was then placed in paraffin?</b></p> <p>19 A. I believe so.</p> <p>20 <b>Q. Is there any remaining of the mesh</b></p> <p>21 <b>explant that was not put in paraffin?</b></p> <p>22 A. I don't think so. It depends. If</p> <p>23 it's a large piece, which I don't suspect it is,</p> <p>24 there are some remnants which are stored in</p> <p>25 formalin. In this case, probably everything went</p>
<p style="text-align: right;">Page 63</p> <p>1 for making presentations or publishing the papers.</p> <p>2 <b>Q. Okay. Let's go back to page 83.</b></p> <p>3 <b>83 again is the mesh fiber that you looked at under</b></p> <p>4 <b>light microscopy 40 minutes to an hour after it was</b></p> <p>5 <b>removed and before it was stored in formalin,</b></p> <p>6 <b>correct?</b></p> <p>7 A. That is correct.</p> <p>8 <b>Q. Where is that fiber today?</b></p> <p>9 A. It's embedded in formalin. The</p> <p>10 specimen went into formalin -- sorry. The specimen</p> <p>11 went to formalin and now it's embedded in paraffin.</p> <p>12 <b>Q. Why is it in paraffin?</b></p> <p>13 A. To take histological section.</p> <p>14 <b>Q. Have you taken histological</b></p> <p>15 <b>sections of it yet? Have you taken histological</b></p> <p>16 <b>sections of this mesh fiber yet?</b></p> <p>17 A. Yes, I did.</p> <p>18 <b>Q. Are those reported anywhere?</b></p> <p>19 A. What do you mean? This was St.</p> <p>20 Michael's Hospital patient. I described it, and I</p> <p>21 reported whatever I saw in the microscope.</p> <p>22 <b>Q. Okay.</b></p> <p>23 A. It's not within the litigation</p> <p>24 process. It's a patient outside of litigation and</p> <p>25 the only way this picture made it into this report</p>	<p style="text-align: right;">Page 65</p> <p>1 to paraffin.</p> <p>2 <b>Q. So there still exists some mesh</b></p> <p>3 <b>material in paraffin that could be available for</b></p> <p>4 <b>analysis; fair?</b></p> <p>5 MR. ORENT: Objection.</p> <p>6 THE WITNESS: For histology?</p> <p>7 BY MR. THOMAS:</p> <p>8 <b>Q. Yes.</b></p> <p>9 A. Yes.</p> <p>10 <b>Q. And have you prepared histological</b></p> <p>11 <b>slides of the mesh fibers that are contained on</b></p> <p>12 <b>page 83 of your report?</b></p> <p>13 A. Yes.</p> <p>14 MR. ORENT: Objection.</p> <p>15 BY MR. THOMAS:</p> <p>16 <b>Q. As I understand it, they are not</b></p> <p>17 <b>part of your report in this case, true?</b></p> <p>18 A. No. As I said, this patient has</p> <p>19 nothing to do with this report. The only mechanism</p> <p>20 that this paper appeared in this report because it</p> <p>21 was in peer-reviewed publication, that's it. Why</p> <p>22 are we talking about this patient? I don't</p> <p>23 understand.</p> <p>24 <b>Q. And if I wanted you to produce the</b></p> <p>25 <b>paraffin with the remaining mesh and the slides</b></p>

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<p style="text-align: right;">Page 66</p> <p>1 <b>that you have for this mesh, which is depicted on</b>  2 <b>83, would you do that for me?</b>  3 MR. ORENT: Objection. I think you  4 need to deal with the hospital and privacy laws of  5 Canada. I don't think Dr. Iakovlev owns that  6 property, nor --  7 MR. THOMAS: If he's not going to do  8 it, that's all I want to know.  9 THE WITNESS: No, I will not do that.  10 As I said, the paper is published. It's public,  11 that is why it made it into this report.  12 Everything which belong to St. Michael's and  13 individual patients outside of litigation has  14 nothing to do with this report.  15 BY MR. THOMAS:  16 <b>Q. Did you wait until it was</b>  17 <b>published before you used it in the report?</b>  18 A. Yes, I did. I mean, it was  19 published by the time I produced the report.  20 <b>Q. Okay. Did you use it in any other</b>  21 <b>report prior to the time that it was published in</b>  22 <b>the journal?</b>  23 A. I don't think so.  24 <b>Q. That would have been</b>  25 <b>inappropriate?</b></p>	<p style="text-align: right;">Page 68</p> <p>1 They see if there can be any harm to the patients,  2 then they approve your methodology.  3 <b>Q. And do you have a written document</b>  4 <b>from the REB that approves your mesh research work?</b>  5 A. Yes.  6 <b>Q. Is there more than one that you</b>  7 <b>have from there?</b>  8 A. There was renewal.  9 <b>Q. Did you submit an application to</b>  10 <b>them for this REB approval?</b>  11 A. Yes, of course.  12 <b>Q. And you have that application</b>  13 <b>still?</b>  14 A. Yes, I should.  15 <b>Q. What other documents did you have</b>  16 <b>in your possession related to your request for, or</b>  17 <b>their approval of your research in meshes?</b>  18 A. Nothing. Just application and  19 their approval letter.  20 <b>Q. Did you have to appear before the</b>  21 <b>REB to represent on your research?</b>  22 A. No, it's a simple, it is a very  23 simple project. I don't do anything to the  24 patient. I don't do anything specific.  25 I do exactly what I do every day, so it</p>
<p style="text-align: right;">Page 67</p> <p>1 A. Before it was published, or  2 accepted -- it depends. It's my research project  3 and I'm covered by REB.  4 So if it's within my research and  5 knowledge it would be appropriate because I conduct  6 research, that's information I extract during my  7 research.  8 <b>Q. So if you used it in a report</b>  9 <b>against Ethicon prior to the time that it was</b>  10 <b>published in the journal, that's okay, because it's</b>  11 <b>a product of your independent research under the</b>  12 <b>REB; is that correct?</b>  13 A. Yes.  14 (Reporter sought clarification.)  15 A. Research Ethics Board.  16 <b>Q. Is the Research Ethics Board the</b>  17 <b>Canadian equivalent of the American Institutional</b>  18 <b>Review Board; do you know?</b>  19 A. No, no.  20 <b>Q. What's the difference?</b>  21 A. Ethics board is individual for  22 specific institutions. Each institution has their  23 specific research ethics board.  24 <b>Q. What does the REB do?</b>  25 A. They review your application.</p>	<p style="text-align: right;">Page 69</p> <p>1 was straightforward. It couldn't be any hard, just  2 examining histologically.  3 <b>Q. Let's take a break.</b>  4 <b>-- RECESS AT 10:19 --</b>  5 <b>-- UPON RESUMING AT 10:26 --</b>  6 BY MR. THOMAS:  7 <b>Q. Doctor, going back to the images</b>  8 <b>on page 83 of your report, did you write a</b>  9 <b>pathology report of your findings for your review</b>  10 <b>of the histology?</b>  11 A. Probably I did. Maybe I haven't  12 completed it yet. With the meshes, I'm slow, so I  13 could have completed the report, could have not. I  14 don't remember now.  15 <b>Q. What's your practice for doing a</b>  16 <b>pathology report for a patient in the hospital who</b>  17 <b>is not involved in medical-legal? Do you turn that</b>  18 <b>around pretty quickly?</b>  19 A. What do you mean is not involved  20 in medical-legal?  21 <b>Q. I thought you told me this was not</b>  22 <b>a medical-legal case, this mesh that's on page 83</b>  23 <b>of your report?</b>  24 A. That's correct.  25 <b>Q. So, have you done a pathology</b></p>

18 (Pages 66 to 69)

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<p style="text-align: right;">Page 70</p> <p>1 <b>report for this patient based on your review of the</b>  2 <b>histology of her mesh?</b>  3 A. Doesn't matter medical-legal or  4 not medical-legal, when I collect mesh specimens  5 because my work is done so slow, I think and it  6 takes me time. It has nothing to do with  7 medical-legal or not. The difference is mesh  8 versus no mesh.  9 <b>Q. Have you prepared any -- have you</b>  10 <b>dictated anything related to the histology from the</b>  11 <b>mesh ex-plant that's depicted on page 83 of your</b>  12 <b>report?</b>  13 MR. ORENT: Objection.  14 THE WITNESS: I don't remember.  15 BY MR. THOMAS:  16 <b>Q. Have you written anything about</b>  17 <b>your review of the histology from the explanted</b>  18 <b>mesh that's based on page 83 of your report?</b>  19 MR. ORENT: Objection.  20 THE WITNESS: As I said, I don't  21 remember. I've written something, because there  22 was a gross description at least there at the  23 beginning of the report. Maybe it's signed out, I  24 don't remember now. I use exactly the same format  25 for all mesh specimens litigation, non litigation.</p>	<p style="text-align: right;">Page 72</p> <p>1 Now we're getting into completely  2 different area and I said I'm not getting  3 comfortable in getting into confidential  4 information of a St. Michael's patient.  5 <b>Q. I'm trying to figure out whether</b>  6 <b>anything in writing exists to your knowledge that</b>  7 <b>describes the findings you made based upon</b>  8 <b>histological review of this explanted mesh.</b>  9 MR. ORENT: I think he's answered those  10 questions. I think he's gone far beyond his  11 comfort level. Let's move on.  12 MR. THOMAS: Are you instructing him  13 not to answer?  14 MR. ORENT: I'm not. However, if he  15 believes that he's confined by Canada's  16 confidentiality laws it's up to him in terms of his  17 knowledge, and what he can share as a doctor over a  18 patient who is not at issue in this lawsuit and not  19 put their medicals at issue.  20 THE WITNESS: As I said, I'm not  21 comfortable getting into further details. I think  22 it's inappropriate. This picture appeared in the  23 report because it was published.  24 BY MR. THOMAS:  25 <b>Q. Doctor, on page 8 through 11 of</b></p>
<p style="text-align: right;">Page 71</p> <p>1 BY MR. THOMAS:  2 <b>Q. I understand that.</b>  3 A. And because there are so many  4 items I'm checking it takes me time and I don't  5 want to do it in a rush.  6 With cancer cases it is a different  7 story. I rush, I try to make sure diagnostic  8 process is not involved. In this case the mesh is  9 out already so there is no pressure.  10 <b>Q. So to your knowledge, you don't</b>  11 <b>know whether the doctor or the patient had the</b>  12 <b>benefit of your pathological review of the</b>  13 <b>histology, correct?</b>  14 A. I think I described it for the  15 physician.  16 <b>Q. How did you describe it to her?</b>  17 <b>In writing or voicemail or person to person?</b>  18 A. I don't remember now. I'm not  19 sure where we're going with this, this is  20 confidential, and I'm not comfortable getting into  21 confidential information of a St. Michael's  22 Hospital patient.  23 The paper has been published and the  24 picture made it in the report after the publication  25 was peer reviewed and accepted.</p>	<p style="text-align: right;">Page 73</p> <p>1 <b>your report, you have a section titled</b>  2 <b>"Polypropylene Degradation and Review of Ethicon's</b>  3 <b>Internal Documents"?</b>  4 A. That is correct.  5 <b>Q. How did you determine what</b>  6 <b>documents to review from Ethicon?</b>  7 A. I asked to send me anything which  8 was available pertinent to polypropylene  9 degradation, specifically if Ethicon scientists  10 performed testing using similar technology and  11 methodology, histology mainly.  12 <b>Q. Did you rely on counsel to provide</b>  13 <b>to you the documents that you reviewed?</b>  14 A. Yes.  15 <b>Q. Did you produce for us on</b>  16 <b>Exhibit 4 all of the documents that you reviewed?</b>  17 A. Yes, I did.  18 <b>Q. Were there other documents that</b>  19 <b>plaintiff's counsel supplied to you that you did</b>  20 <b>not include on Exhibit 4?</b>  21 A. Not to the best of my knowledge.  22 <b>Q. All right. You also refer to</b>  23 <b>deposition testimony of Thomas Barbolt?</b>  24 A. Yes.  25 <b>Q. Is Dr. Barbolt's deposition on</b></p>

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<p style="text-align: right;">Page 74</p> <p>1 <b>Exhibit 4?</b></p> <p>2 A. Yes, it is.</p> <p>3 <b>Q. Do you remember how many days his</b></p> <p>4 <b>deposition was?</b></p> <p>5 A. I think there were two days.</p> <p>6 <b>Q. Did you read the whole thing?</b></p> <p>7 A. I read most of the deposition.</p> <p>8 Skimmed, I mean it's really long document.</p> <p>9 <b>Q. Do you recall what his job was at</b></p> <p>10 <b>Ethicon?</b></p> <p>11 A. I don't recall now.</p> <p>12 <b>Q. Do you know what his training was?</b></p> <p>13 A. No.</p> <p>14 <b>Q. Do you know what kind of testing</b></p> <p>15 <b>Dr. Barbolt conducted while he was at Ethicon?</b></p> <p>16 A. I don't remember now.</p> <p>17 <b>Q. Do you know whether he conducted</b></p> <p>18 <b>any animal testing of mesh?</b></p> <p>19 A. I saw documents of animal testing,</p> <p>20 many documents. If he was part of all of them or</p> <p>21 some of them, I don't remember.</p> <p>22 <b>Q. Do you know whether he conducted</b></p> <p>23 <b>any tissue reaction studies?</b></p> <p>24 A. I don't remember that, no.</p> <p>25 <b>Q. Do you know whether Dr. Barbolt</b></p>	<p style="text-align: right;">Page 76</p> <p>1 BY MR. THOMAS:</p> <p>2 <b>Q. What testing do you recall</b></p> <p>3 <b>reviewing as a part of your review of the Ethicon</b></p> <p>4 <b>documents in the case?</b></p> <p>5 A. As I said, I was focused mainly on</p> <p>6 histological examination but I also skimmed through</p> <p>7 the testing which was done using scanning electron</p> <p>8 microscopy and just regular light microscopy.</p> <p>9 <b>Q. Did you have see any histological</b></p> <p>10 <b>examination of what was described as cracked</b></p> <p>11 <b>polypropylene sutures?</b></p> <p>12 A. Yes.</p> <p>13 <b>Q. And what did you find in your</b></p> <p>14 <b>review of the histological examination?</b></p> <p>15 A. I was really surprised. They</p> <p>16 found exactly what I found 30 years before I did.</p> <p>17 I did it independently; I didn't have those</p> <p>18 documents before. So I thought I was Columbus, but</p> <p>19 I guess I wasn't.</p> <p>20 <b>Q. And you say they found exactly</b></p> <p>21 <b>what you found?</b></p> <p>22 A. Yes, exactly the same. Even</p> <p>23 arrows were so much like mine.</p> <p>24 <b>Q. What was it that they found which</b></p> <p>25 <b>was exactly what you found?</b></p>
<p style="text-align: right;">Page 75</p> <p>1 <b>compiled and reviewed testing on Prolene</b></p> <p>2 <b>polypropylene from the 1960s to the present?</b></p> <p>3 A. As I said, there were many</p> <p>4 documents and it's hard for me to remember now.</p> <p>5 <b>Q. Do you know -- strike that. Is it</b></p> <p>6 <b>fair to understand that to the extent Dr. Barbolt</b></p> <p>7 <b>presented any testing in his depositions you have</b></p> <p>8 <b>not reviewed that testing?</b></p> <p>9 MR. ORENT: Objection.</p> <p>10 THE WITNESS: As I said, I was asking</p> <p>11 counsel to provide specific information, specific</p> <p>12 topics. So they provided this information and I</p> <p>13 received a number of documents.</p> <p>14 I specifically didn't even check</p> <p>15 whoever signed this, who were the names.</p> <p>16 BY MR. THOMAS:</p> <p>17 <b>Q. Did you review any of the testing</b></p> <p>18 <b>Dr. Barbolt reviewed in his deposition?</b></p> <p>19 A. As I said --</p> <p>20 MR. ORENT: Objection.</p> <p>21 THE WITNESS: I don't remember the</p> <p>22 names. The only reason I remember his name because</p> <p>23 it was the only deposition I had specifically for</p> <p>24 that specific subject.</p> <p>25</p>	<p style="text-align: right;">Page 77</p> <p>1 A. There is a degradation bark and it</p> <p>2 retains histological dyes, and it also retains the</p> <p>3 granules of blue fibers. And they also used</p> <p>4 polarized light.</p> <p>5 I think you asked me earlier in the</p> <p>6 deposition who was using polarized light before.</p> <p>7 Your scientists were.</p> <p>8 <b>Q. Is it your opinion that Ethicon</b></p> <p>9 <b>conclusively found exactly what you found?</b></p> <p>10 A. Yes.</p> <p>11 <b>Q. And that's based on the documents</b></p> <p>12 <b>that have been provided to you?</b></p> <p>13 A. Yes.</p> <p>14 <b>Q. Did you see any histological</b></p> <p>15 <b>examination of the sutures that analyze to the</b></p> <p>16 <b>extent to which it created any risk of harm to</b></p> <p>17 <b>patients?</b></p> <p>18 A. I don't think I understand your</p> <p>19 question.</p> <p>20 <b>Q. What don't you understand about</b></p> <p>21 <b>it?</b></p> <p>22 MR. ORENT: Objection.</p> <p>23 BY MR. THOMAS:</p> <p>24 <b>Q. Let me start over again. During</b></p> <p>25 <b>the course of your review of Ethicon documents, did</b></p>

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<p>1 you review any documents where Ethicon scientists</p> <p>2 reviewed histological slides of tissue samples</p> <p>3 containing mesh that was described as having</p> <p>4 cracks?</p> <p>5 A. Yes, I did.</p> <p>6 Q. And do you recall what the tissue</p> <p>7 reaction was that they described in those samples?</p> <p>8 A. Yes, I do.</p> <p>9 Q. And what is that?</p> <p>10 A. It is the same thing which I saw,</p> <p>11 fibrosis foreign body reaction formation.</p> <p>12 Q. Do you know how the description</p> <p>13 they found in their documents compares to what the</p> <p>14 tissue reaction as described for Prolene sutures at</p> <p>15 the time that it was approved by the FDA in 1969?</p> <p>16 MR. ORENT: Objection.</p> <p>17 THE WITNESS: The documents I reviewed</p> <p>18 they were dated in '80s.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. I understand that.</p> <p>21 A. They had exactly the same</p> <p>22 description as earlier papers or papers after that.</p> <p>23 So I don't think there is any difference in any of</p> <p>24 the descriptions.</p> <p>25 Q. Okay.</p>	<p>1 THE WITNESS: I see it removed.</p> <p>2 Probably it's used for hernia mesh as well.</p> <p>3 Prolene or Marlex, I'm not sure. There are newer</p> <p>4 meshes coming on the market.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Does St. Michael's use Prolene</p> <p>7 polypropylene mesh for the treatment of stress</p> <p>8 urinary incontinence in TVT and TVT-O?</p> <p>9 MR. ORENT: Objection.</p> <p>10 THE WITNESS: I don't think so.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Do you know?</p> <p>13 A. Maybe in the past. Right now I</p> <p>14 just receive them when they're removed.</p> <p>15 They've been using them before. I</p> <p>16 don't know if they still using it right now.</p> <p>17 Q. Have you told St. Michael's to</p> <p>18 stop using Prolene polypropylene sutures?</p> <p>19 A. Not sutures. I talk to</p> <p>20 gynecologist. I show them what my research found,</p> <p>21 what I found, let them know, what's, what's my</p> <p>22 opinion about this.</p> <p>23 Q. Who did you talk to at St.</p> <p>24 Michael's about that?</p> <p>25 A. Our gynecologist.</p>
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<p>1 A. Either at time of filing of the</p> <p>2 FDA application or after, it's all the same.</p> <p>3 Q. And the findings that they found</p> <p>4 in the '80s and the findings that they found</p> <p>5 earlier, and the findings that they reported later</p> <p>6 are just the same as yours are?</p> <p>7 A. Pretty much.</p> <p>8 Q. Okay. You say on page 9 of your</p> <p>9 report at the end of the first paragraph:</p> <p>10 "An important conclusion should</p> <p>11 be made that if chemical and</p> <p>12 physical properties have material</p> <p>13 change while it is in the body, it</p> <p>14 should not be used for permanent</p> <p>15 applications and for anatomical</p> <p>16 sites from which the devices cannot</p> <p>17 be safely removed."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes, you did.</p> <p>20 Q. Does St. Michael's use Prolene</p> <p>21 sutures?</p> <p>22 A. Yes, I understand they do.</p> <p>23 Q. Does St. Michael's use Prolene</p> <p>24 hernia mesh?</p> <p>25 MR. ORENT: Objection.</p>	<p>1 Q. I'm sorry?</p> <p>2 A. Our gynecologist.</p> <p>3 Q. And who is that?</p> <p>4 A. I don't think I can go there.</p> <p>5 Again, I'm not comfortable getting into specific</p> <p>6 information which is not relevant to my report.</p> <p>7 Q. What did you tell that person?</p> <p>8 A. I shared my research, what I</p> <p>9 shared in my papers.</p> <p>10 Q. Did you tell them that St.</p> <p>11 Michael's should not use Prolene polypropylene?</p> <p>12 A. I'm not making any guidelines.</p> <p>13 I'm not a regulating body. As a researcher I can</p> <p>14 share my opinion, my findings, with colleagues.</p> <p>15 And that's what I do in my publications and that's</p> <p>16 what I did in my personal conversations and</p> <p>17 personal contacts with St. Michael's physicians.</p> <p>18 Q. When did you have those</p> <p>19 conversations?</p> <p>20 A. Throughout. I've been involved in</p> <p>21 these meshes for the last year, maybe over a year,</p> <p>22 I don't remember now. First it was hernia</p> <p>23 surgeons, then gynecologists.</p> <p>24 Q. So you've spoken to hernia</p> <p>25 surgeons at St. Michael's about the use of</p>

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<p style="text-align: right;">Page 82</p> <p>1 polypropylene mesh?</p> <p>2 A. That's how it came, it came</p> <p>3 through hernia surgeons. The whole research</p> <p>4 project came through hernia surgeons.</p> <p>5 Q. Do you know whether hernia</p> <p>6 surgeons at St. Michael's are still using</p> <p>7 polypropylene mesh?</p> <p>8 A. Probably they do. But not all of</p> <p>9 them. Some of them do, some of them don't.</p> <p>10 Q. Do you know whether St. Michael's</p> <p>11 continues to use polypropylene mesh for the</p> <p>12 treatment of stress urinary incontinence?</p> <p>13 A. As I said, I know they've used it.</p> <p>14 I don't know if they're still using it right now as</p> <p>15 we speak.</p> <p>16 Q. Did you ever tell them as a</p> <p>17 scientist and pathologist that they should stop</p> <p>18 using Prolene polypropylene mesh because it was</p> <p>19 harming their patients?</p> <p>20 MR. ORENT: Objection.</p> <p>21 THE WITNESS: I described pathological</p> <p>22 findings and I disclosed everything I found in the</p> <p>23 specimens which were coming to me as part of St.</p> <p>24 Michael's Hospital and what I found during the</p> <p>25 course of my research. Yes, I did disclose all of</p>	<p style="text-align: right;">Page 84</p> <p>1 St. Michael's, isn't there?</p> <p>2 A. Yes, but not all of them are</p> <p>3 dealing with stress urinary incontinence. There is</p> <p>4 a degree of specialization. Some of them do it,</p> <p>5 sometimes some people specialize more in the field.</p> <p>6 Q. There's more than one hernia</p> <p>7 surgeon, isn't there?</p> <p>8 A. Yes, correct.</p> <p>9 Q. Is there someone over both of</p> <p>10 those specialties that can determine that the</p> <p>11 hospital should not use polypropylene sutures or</p> <p>12 mesh?</p> <p>13 A. I don't know if it can be done.</p> <p>14 Q. Have you ever made an effort to do</p> <p>15 that?</p> <p>16 A. To stop them?</p> <p>17 Q. (Nods).</p> <p>18 A. As I said, I don't know if it can</p> <p>19 be done.</p> <p>20 Q. Have you ever made an effort to</p> <p>21 stop St. Michael's Hospital from using Prolene</p> <p>22 sutures or Prolene mesh other than the</p> <p>23 conversations you had with a gynecologist and a</p> <p>24 hernia surgeon?</p> <p>25 A. No.</p>
<p style="text-align: right;">Page 83</p> <p>1 this.</p> <p>2 They are independent practitioners.</p> <p>3 They collect information from peer-reviewed</p> <p>4 studies. They see the evidence which is published.</p> <p>5 I'm one piece of the puzzle, one piece of the</p> <p>6 information.</p> <p>7 They make their own decision. They're</p> <p>8 licensed physicians and there are regulating bodies</p> <p>9 which give guidelines.</p> <p>10 Again, they are free to use my</p> <p>11 guidelines in my research or anything else and</p> <p>12 advise their patients what is the best course and</p> <p>13 what can be complications.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Who was the person at St.</p> <p>16 Michael's who makes the decision whether to use</p> <p>17 polypropylene mesh?</p> <p>18 A. Each individual physician makes</p> <p>19 own decisions after discussion with the patient.</p> <p>20 That's my understanding.</p> <p>21 I don't think there is any guiding body</p> <p>22 in specific hospital which can stop physicians from</p> <p>23 using specific device.</p> <p>24 Q. When you said you went to the</p> <p>25 gynecologist, there's more than one gynecologist at</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. Thank you.</p> <p>2 What did Dr. Barbolt say about the</p> <p>3 clinical significance, if any, of surface cracks on</p> <p>4 polypropylene implanted in the dog study?</p> <p>5 A. I don't remember now.</p> <p>6 Q. What did Dr. Barbolt say about the</p> <p>7 molecular weight of the Prolene sutures implanted</p> <p>8 in the dog study after seven years?</p> <p>9 A. I don't remember now.</p> <p>10 Q. What did he say about the --</p> <p>11 strike that. What did Dr. Barbolt say about the</p> <p>12 physical properties of the Prolene sutures</p> <p>13 implanted in the dogs after seven years?</p> <p>14 MR. ORENT: Objection.</p> <p>15 THE WITNESS: I don't remember now.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Page 11 of your report. You talk</p> <p>18 about effect on the tissue, we're talking about</p> <p>19 pain -- sorry, I'm on the wrong page.</p> <p>20 It's on page 12, I'm sorry.</p> <p>21 A. Okay.</p> <p>22 Q. Page 12, it says:</p> <p>23 "It is important to note that</p> <p>24 in hernia surgery, chronic pain</p> <p>25 after mesh repair is a growing</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1           <b>problem. Prophylactic neurectomy is</b>  2           <b>offered as a method to reduce</b>  3           <b>incidence of pain after mesh</b>  4           <b>repair."</b>  5           <b>What is a prophylactic neurectomy?</b>  6           A. When you cut the nerves before you  7 put the mesh in anticipating the mesh is going to  8 cause pain.  9           <b>Q. When you say cut the nerve, what</b>  10          <b>kind of nerve are you going to cut in the hernia</b>  11          <b>surgery?</b>  12          A. There are three main nerves  13 branches: Genitofemoral, inguinal, um, some names,  14 um...  15          <b>Q. Any other nerves as a part of the</b>  16          <b>hernia surgery?</b>  17          A. There are three branches, which  18 can be identified visually. They are thicker  19 trunks. There is a variability between people, but  20 they're called triple neurectomy because in most  21 people there will be three branches supplying  22 innervation to the area.  23          <b>Q. So tell me what is done and why</b>  24          <b>it's done in hernia surgery with prophylactic</b>  25          <b>neuroectomy?</b></p>	<p style="text-align: right;">Page 88</p> <p>1           So historically, first there were  2 meshes put in, and then more meshes put in, and  3 then more patients started coming back as chronic  4 pain, taking the mesh out was difficult, there was  5 large defect.  6           So somebody came up with the idea,  7 let's leave the mesh in but try to denervate the  8 area, either bury the nerves with some chemicals  9 like alcohol, or put nerve blocks, which was an  10 effective strategy.  11          You anesthetize the area, so the nerve  12 doesn't work for few weeks, and then the pain would  13 be gone.  14          And then somebody came up with this  15 idea of more permanent denervation, when the area  16 is anesthetized by cutting the nerve.  17          And then first surgeons try to do  18 neurectomy or transection of the nerve after mesh  19 repair, and after some experience they figure out  20 it's really hard to do to find the nerves from the  21 old scarred area.  22          So somebody offered, okay, if we  23 anticipate the pain developing from mesh, let's cut  24 the nerve before, when the area is clean and there  25 are no scarring or mesh in the area.</p>
<p style="text-align: right;">Page 87</p> <p>1           A. It depends. There's different  2 techniques. Either the branches can be cut in the  3 area, so there will be three branches identified  4 and transected, buried in muscle. The stumps will  5 be buried in muscle.  6          It could be also arthroscopic  7 techniques when they go and try and cut the nerve  8 trunks closer to the spinal cord.  9          Then I'm not sure if it will be three  10 branches, because if you go proximally it will be  11 less branches, they will all merge into larger  12 trunks. So you cannot call it triple neurectomy at  13 that level.  14          But the basic rule, we try to identify  15 supply innervation, either larger trunk or smaller  16 branches, transect them and bury the stump in the  17 muscles, so it doesn't form traumatic neuroma.  18          It's done because you want to denervate  19 the area where you anticipate the mesh is going to  20 cause pain.  21          <b>Q. Why is it important to note the</b>  22          <b>prophylactic neurectomy in your report?</b>  23          A. Because when chronic pain due to  24 mesh occurs, going back into the scarred area,  25 obstructed by the mesh, proved to be hard.</p>	<p style="text-align: right;">Page 89</p> <p>1           <b>Q. Is that an accepted surgical</b>  2           <b>technique to do a nerve neurectomy prior to mesh</b>  3           <b>implantation?</b>  4           A. Yes, it is. It's offered, it's  5 published and there are results.  6           <b>Q. Is that a common occurrence with</b>  7           <b>mesh implantation?</b>  8           MR. ORENT: Objection. Vague.  9           THE WITNESS: Depends on the surgeons.  10 Some surgeons believe in this and they do it.  11 Depends probably on the group of surgeons' practice  12 habits.  13           BY MR. THOMAS:  14           <b>Q. Right above that section on the</b>  15           <b>prophylactic neurectomy, you discuss the mesh scar</b>  16           <b>complex and its "interlocking and</b>  17           <b>compartmentalizing nature". What is the</b>  18           <b>interlocking and compartmentalizing nature of the</b>  19           <b>mesh scar complex?</b>  20           A. So if we look at the mesh, mesh is  21 a structure, three-dimensional structure made out  22 of mesh fibers or mesh filaments.  23           So filament of fiber, circles around,  24 loops around, and then it forms in pores, and in  25 these tissues. And each pore has 360 degrees of</p>

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<p style="text-align: right;">Page 90</p> <p>1 surrounding fibers, that's why it is a pore.</p> <p>2 So it becomes a compartment. An area</p> <p>3 which is surrounded by something or a physical</p> <p>4 structure with volume inside, that is a</p> <p>5 compartment. So the mesh introduces all these</p> <p>6 micro compartments.</p> <p>7 <b>Q. There aren't walls around each of</b></p> <p>8 <b>these compartments, are there?</b></p> <p>9 A. Yes, there are. Fibers, mesh</p> <p>10 fibers, they form the walls of this compartment.</p> <p>11 <b>Q. But they don't totally encapsulate</b></p> <p>12 <b>-- strike that.</b></p> <p>13 <b>The compartment though, has an opening</b></p> <p>14 <b>on either side much like a screen, correct?</b></p> <p>15 A. Yeah, more like a screen or a</p> <p>16 tube. To a degree, because mesh is not completely</p> <p>17 flat, it's a more of a three-dimensional. If you</p> <p>18 go with microscopic level, it's three-dimensional.</p> <p>19 So I would compare it with each pore as</p> <p>20 a very complex irregular tube, more or less.</p> <p>21 <b>Q. My point is, instead of a</b></p> <p>22 <b>compartment it is a tube with openings on either</b></p> <p>23 <b>side?</b></p> <p>24 A. A compartment is a tube. All</p> <p>25 compartments in human body are tubes.</p>	<p style="text-align: right;">Page 92</p> <p>1 When it's used with scar it cannot so</p> <p>2 that is lost. When it's incorporated in scar</p> <p>3 tissue, the movement and bendability of fibers is</p> <p>4 limited.</p> <p>5 <b>Q. Let me ask you a question here; I</b></p> <p>6 <b>don't mean to interrupt you. Is folding or curling</b></p> <p>7 <b>a necessary part of mesh stiffening?</b></p> <p>8 A. No. It's one of the processes</p> <p>9 which increases mesh stiffness if you compare it</p> <p>10 with the flat product.</p> <p>11 <b>Q. So you can have, as far as you're</b></p> <p>12 <b>concerned, mesh stiffening if the mesh does not</b></p> <p>13 <b>fold or curl?</b></p> <p>14 A. Then other mechanisms will set in.</p> <p>15 <b>Q. But the first one deals with</b></p> <p>16 <b>folding, curling and then the scar that you just</b></p> <p>17 <b>described?</b></p> <p>18 A. Yes.</p> <p>19 <b>Q. I didn't mean to interrupt you.</b></p> <p>20 <b>Is there anything else you wanted to say about that</b></p> <p>21 <b>mechanism?</b></p> <p>22 A. And then slowly over the years,</p> <p>23 the degradation layer will start building up and we</p> <p>24 know it's brittle. Like any other plastic, we see</p> <p>25 over time it starts cracking. It becomes harder</p>
<p style="text-align: right;">Page 91</p> <p>1 <b>Q. That has an opening on either</b></p> <p>2 <b>side?</b></p> <p>3 A. Yes, that's how they are in the</p> <p>4 body. If we talk about tunnel syndromes in the</p> <p>5 hand or in the chest, all these compartments form a</p> <p>6 tube.</p> <p>7 And the tube lets nerves and blood</p> <p>8 vessels through and if compartment syndrome occurs,</p> <p>9 it compromises the nerves in the vessel, in the</p> <p>10 tube-like structure.</p> <p>11 <b>Q. Doctor, in your report you</b></p> <p>12 <b>discussed the concept of mesh stiffening?</b></p> <p>13 A. Yes, I did.</p> <p>14 <b>Q. Please tell me how mesh stiffens?</b></p> <p>15 A. Immediately after placement, it</p> <p>16 can fold and curve. So two layers or three layers</p> <p>17 of mesh is different than one layer. So this is</p> <p>18 initial step, if it folds or curls or wrinkles</p> <p>19 immediately after placement.</p> <p>20 Then next step which will increase</p> <p>21 stiffness of the structure is scar encapsulation.</p> <p>22 So scar immobilizes the fibers in the structures so</p> <p>23 they can not move inside the elasticity of the</p> <p>24 meshes, mainly because of the bending ability of</p> <p>25 the fibers and movement within the structure.</p>	<p style="text-align: right;">Page 93</p> <p>1 and less flexible and it breaks.</p> <p>2 <b>Q. The degradation layer you</b></p> <p>3 <b>described is four to five microns?</b></p> <p>4 A. It depends. It depends how long</p> <p>5 it's been in the body.</p> <p>6 <b>Q. Is four to five microns about the</b></p> <p>7 <b>largest you've seen?</b></p> <p>8 A. No, I've seen up to seven or</p> <p>9 eight. Depends on the type of mesh, I guess --</p> <p>10 <b>Q. Well, Prolene polypropylene, what</b></p> <p>11 <b>is the largest you've seen?</b></p> <p>12 A. It's hard to say because it's for</p> <p>13 -- currently that mesh is -- 80 percent of the time</p> <p>14 I don't actually know what the product is.</p> <p>15 <b>Q. 80 percent of the time you don't</b></p> <p>16 <b>know what the product is?</b></p> <p>17 A. Yes.</p> <p>18 <b>Q. And the reason why I ask is, in</b></p> <p>19 <b>all the reports I've seen, I've never seen you give</b></p> <p>20 <b>an opinion that is greater than five microns to a</b></p> <p>21 <b>Prolene mesh?</b></p> <p>22 A. That's just happened with any</p> <p>23 litigation process, but I have over 300 meshes in</p> <p>24 my office.</p> <p>25 I'm just telling you the thickest bark</p>

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<p>1 as far as I remember was up to seven, probably just 2 over seven microns thick. 3 And I think it was a hernia mesh and 4 for hernia meshes, when they've been in the body 5 for like 12 or 14 years, it's very difficult to 6 trace what type of mesh was put in. 7 <b>Q. Your best recollection insofar as</b> 8 <b>you're dealing with Prolene mesh for the treatment</b> 9 <b>of stress urinary incontinence, the largest you've</b> 10 <b>seen is five microns, correct?</b> 11 MR. ORENT: Objection. 12 THE WITNESS: Probably six, I don't 13 remember now. 14 BY MR. THOMAS: 15 <b>Q. This bark, as you've described it,</b> 16 <b>by definition is cracking?</b> 17 A. Yes. 18 <b>Q. And when you get past the bark</b> 19 <b>layer the interior of the polypropylene as best as</b> 20 <b>you can tell is unaffected?</b> 21 A. Yes. 22 <b>Q. Okay.</b> 23 A. The core of the fibers remains, at 24 least, the same by my methods. 25 <b>Q. And by your methods, as far as you</b></p>	<p>1 MR. ORENT: Objection. 2 THE WITNESS: For litigation cases? 3 Meshes come in formalin, that is correct. But in 4 St. Michael's Hospital, when they receive mesh, as 5 I mentioned, everybody knows I'm the mesh guy. 6 They call me when they receive a mesh, sometimes I 7 receive them fresh. 8 BY MR. THOMAS: 9 <b>Q. Do you have any documents, images</b> 10 <b>or any other information about meshes that you've</b> 11 <b>received fresh, without formalin, that show folding</b> 12 <b>or curling?</b> 13 MR. ORENT: Objection to form. 14 THE WITNESS: I describe them when I 15 receive them. But again, we're going to the St. 16 Michael's Hospital patients and I don't want to go 17 there. I'm not comfortable discussing this 18 confidential information. 19 BY MR. THOMAS: 20 <b>Q. Okay.</b> 21 A. Probably took some pictures at 22 some time. 23 <b>Q. You have not produced those</b> 24 <b>pictures to us?</b> 25 A. They're not in the report.</p>
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<p>1 <b>can tell, past the five microns or so, the physical</b> 2 <b>properties of the polypropylene remain the same,</b> 3 <b>true?</b> 4 MR. ORENT: Objection. 5 THE WITNESS: By my methods, yes. 6 BY MR. THOMAS: 7 <b>Q. Have you described -- you've</b> 8 <b>described two ways that you believe that mesh</b> 9 <b>becomes stiff.</b> 10 <b>Are there any other ways that you</b> 11 <b>believe mesh becomes stiff in the body?</b> 12 A. Three. So multi layering, scar 13 encapsulation and then degradation. No, I don't 14 know any other mechanism for stiffening. 15 <b>Q. And the way that you're able to</b> 16 <b>identify multi layering is when you analyze the</b> 17 <b>mesh after it's been sent to you in formalin from</b> 18 <b>the surgeon, correct?</b> 19 A. As I said, sometimes I receive 20 meshes fresh in saline or not just -- and I see 21 it's folded already. 22 <b>Q. The only polypropylene meshes that</b> 23 <b>you've given us, other than the one that you've</b> 24 <b>given us limited information about, come to you in</b> 25 <b>formalin, correct?</b></p>	<p>1 They're confidential information and I took them 2 because in the course of my work as a pathologist 3 at St. Michael's. 4 <b>Q. Do you have any information about</b> 5 <b>the incidents of folding or curling in mesh</b> 6 <b>implanted -- in Prolene mesh implanted for the</b> 7 <b>treatment of stress urinary incontinence?</b> 8 A. For stress urinary incontinence, 9 the degree of curling is visible in most of the 10 cases. 11 <b>Q. More than half?</b> 12 A. I would say more than half. 13 Again, it depends. Sometimes one piece is curled, 14 the other one is completely flat. 15 <b>Q. And again, these are cases where</b> 16 <b>you've received the mesh in formalin?</b> 17 A. Yes. But I mean we're talking 18 about curling, not curling on the whole specimen. 19 We're talking about curling as it sits in scar 20 tissue. 21 So whatever curling I'm assessing as is 22 significant is on that, that which can -- which is 23 immobilized by scar tissue. 24 So I'm not talking about curling which 25 occurs secondary to fixation. I'm talking about</p>

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<p style="text-align: right;">Page 98</p> <p>1 curling which occurred in the body. I'm able to</p> <p>2 distinguish between one and the other.</p> <p>3 <b>Q. How?</b></p> <p>4 A. I just said. If it's curled and</p> <p>5 it's completely surrounded, integrated in scar</p> <p>6 tissue in curled shape, it occurred in the body.</p> <p>7 If the entire specimen is curled</p> <p>8 together with scar, that could have been an</p> <p>9 artifact. So I immediately disregard the shape or</p> <p>10 the formation which occurred as an artifact.</p> <p>11 <b>Q. Let's go to page 19 of your</b></p> <p>12 <b>report, please.</b></p> <p>13 A. Um-hum.</p> <p>14 <b>Q. I'm going to refer you back to</b></p> <p>15 <b>page 14, because I think that that's the commentary</b></p> <p>16 <b>that you have on that. So you've got 19, which is</b></p> <p>17 <b>the images, and page 14 is the text.</b></p> <p>18 A. Yes.</p> <p>19 <b>Q. Okay. As you look at page 19,</b></p> <p>20 <b>Figure Set 1a is described as:</b></p> <p>21 <b>"A foreign body inflammatory</b></p> <p>22 <b>reaction H&amp;E, 40X images</b></p> <p>23 <b>consolidated cases."</b></p> <p>24 <b>What are you showing here?</b></p> <p>25 A. Foreign body type inflammatory</p>	<p style="text-align: right;">Page 100</p> <p>1 BY MR. THOMAS:</p> <p>2 <b>Q. The images on the left show that</b></p> <p>3 <b>the polypropylene was removed as part of the</b></p> <p>4 <b>microtoming process; correct?</b></p> <p>5 A. Could you repeat that question.</p> <p>6 <b>Q. I'm looking at the figures on the</b></p> <p>7 <b>left, which show the white images, compared to the</b></p> <p>8 <b>right, which show the yellow.</b></p> <p>9 <b>And on the left it shows that the</b></p> <p>10 <b>polypropylene that used to be where the white is</b></p> <p>11 <b>has been removed as a part of the microtoming</b></p> <p>12 <b>process; correct?</b></p> <p>13 A. No, actually, there might be all</p> <p>14 of them present there. They're just clear;</p> <p>15 polypropylene is clear. If it is not degraded,</p> <p>16 it's completely clear.</p> <p>17 If the fibers were blue fibers, they</p> <p>18 would be visible. If it's clear fiber they would</p> <p>19 not.</p> <p>20 So technically, looking at these</p> <p>21 images, we cannot say which hole is the actual MTM,</p> <p>22 and which sort of appear in holes, still contain</p> <p>23 polypropylene. You would need polarized light to</p> <p>24 see that.</p> <p>25 <b>Q. So what can you tell me about the</b></p>
<p style="text-align: right;">Page 99</p> <p>1 reaction.</p> <p>2 <b>Q. Is there anything unusual about</b></p> <p>3 <b>this foreign body reaction?</b></p> <p>4 A. What do you mean unusual?</p> <p>5 <b>Q. Is there anything remarkable about</b></p> <p>6 <b>it? There's a foreign body reaction anytime you</b></p> <p>7 <b>have an implant, correct?</b></p> <p>8 A. Then usually it's not normal</p> <p>9 tissue. Normally there shouldn't be any</p> <p>10 inflammation in the tissue.</p> <p>11 <b>Q. Okay. And so would there be</b></p> <p>12 <b>inflammation regardless of what kind of foreign</b></p> <p>13 <b>body is placed in there?</b></p> <p>14 A. Yes, because having a foreign body</p> <p>15 in the body is not normal thing.</p> <p>16 <b>Q. And so is it fair to say that</b></p> <p>17 <b>Figure Set 1a describes a typical foreign body</b></p> <p>18 <b>reaction to implanted materials?</b></p> <p>19 MR. ORENT: Objection.</p> <p>20 THE WITNESS: I wouldn't say typical,</p> <p>21 although you can use that word. I would say</p> <p>22 non-specific reaction to a foreign body. The body</p> <p>23 is trying to destroy the foreign body because it's</p> <p>24 a noxious stimulus, a noxious or damaging object.</p> <p>25</p>	<p style="text-align: right;">Page 101</p> <p>1 <b>part of the mesh that we're seeing in Figure 1a?</b></p> <p>2 A. Specifically, I don't -- do you</p> <p>3 want me to discuss a specific feature?</p> <p>4 <b>Q. For example, you don't have a</b></p> <p>5 <b>clean cut where you're looking at a perfectly round</b></p> <p>6 <b>portion of the mesh, correct?</b></p> <p>7 MR. ORENT: Objection to form, to the</p> <p>8 use of the term "clean cut".</p> <p>9 THE WITNESS: Some of them are closer</p> <p>10 to perpendicular orientation. Some of them are</p> <p>11 angled.</p> <p>12 BY MR. THOMAS:</p> <p>13 <b>Q. Okay. For example, when you have</b></p> <p>14 <b>a microtoming process and you pull the knife across</b></p> <p>15 <b>the histological slide, sometimes you will create</b></p> <p>16 <b>an artifact by pulling the tissue away from the</b></p> <p>17 <b>polypropylene, correct?</b></p> <p>18 A. Yes, because polypropylene is</p> <p>19 harder than tissue, you can damage tissue during</p> <p>20 cutting.</p> <p>21 <b>Q. And you can't tell if you look at</b></p> <p>22 <b>set 1a whether the polypropylene is there or not;</b></p> <p>23 <b>true?</b></p> <p>24 A. Yes, that's true.</p> <p>25 <b>Q. You can't tell by looking at the</b></p>

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<p style="text-align: right;">Page 102</p> <p>1 <b>figures in set 1a whether those are the actual size</b>  2 <b>of the hole that was occupied by the polypropylene,</b>  3 <b>and whether that is an artifact from microtoming?</b>  4 A. That I can tell you because  5 artifact from microtoming looks completely  6 different. These are holes from fibers.  7 <b>Q. Completely?</b>  8 A. For these specific holes?  9 <b>Q. How can you tell the difference?</b>  10 A. Well, you have to work as I  11 pathologist for so many years and then you can  12 tell.  13 But generally, how we go for that  14 specific feature, it would be shape, rounded shape,  15 oblique, assuming, if we look at this image here --  16 if you want me to point, circle.  17 <b>Q. I'll give you a red pen -- let's</b>  18 <b>give you a blue pen. That will show up better.</b>  19 A. Assuming if we see this tissue,  20 this specific, this is displaced. So when the  21 fiber was not cut, it probably had different  22 position, different orientation. Because it's  23 misplaced, it doesn't completely circle here.  24 <b>Q. Is that an artifact from the</b>  25 <b>microtoming process?</b></p>	<p style="text-align: right;">Page 104</p> <p>1 the mesh fiber.  2 <b>Q. Okay. Let's go now to the next</b>  3 <b>page, page 20. Anything else remarkable about that</b>  4 <b>page, page 19?</b>  5 A. It depends what you want me to  6 describe.  7 <b>Q. Well, I've seen you testify</b>  8 <b>before. And you put these images up on the screen</b>  9 <b>and you tell the jury what you think is remarkable</b>  10 <b>about them?</b>  11 A. Do you want me to go through this  12 description?  13 <b>Q. Do you have anything other than a</b>  14 <b>foreign body reaction, as depicted in the tissue,</b>  15 <b>is there anything other than that that's remarkable</b>  16 <b>about the images on 19?</b>  17 A. This picture is actually good in  18 terms of it shows this layering.  19 So the fibers are surrounded by this  20 dense foreign body type inflammation, and then the  21 inflammation is actually encapsulated by dense scar  22 on the outside, so this very dense pink area is a  23 scar. So it goes on the outside of the  24 inflammation.  25 And then beyond the scar plate, here is</p>
<p style="text-align: right;">Page 103</p> <p>1 A. To a degree.  2 <b>Q. Okay.</b>  3 A. Now, see this empty space here?  4 <b>Q. Mark that A. Mark the first one</b>  5 <b>A, and the next one B, so the record is clear what</b>  6 <b>you've just done.</b>  7 A. (Witness complies).  8 <b>Q. This one will be A. That's the</b>  9 <b>one you've discussed first. The other one you're</b>  10 <b>discussing now is B.</b>  11 A. So this circle labelled A moved  12 during microtomy. It was within the fibers and now  13 it moved, it changed position slightly.  14 The area B appears empty, but it was  15 occupied in vivo, and this is an artifact. Another  16 artifact here is artifact C, which is tissue  17 retraction. Now, if we --  18 <b>Q. And those are all caused by the</b>  19 <b>microtoming process?</b>  20 A. No. Different combination of  21 factors which cause all of this.  22 Now, if we look at the entire opening  23 marked as D, is perfect round shape, no tissue is  24 displaced. So this would be as close as it gets to  25 the area which is occupied by a cross-section of</p>	<p style="text-align: right;">Page 105</p> <p>1 the transition into normal lighter tissue not as  2 densely scarred or densely collagenized.  3 So this picture is a good example of  4 showing this multilayering, sort of onion skin  5 around the mesh fibers.  6 <b>Q. Anything else?</b>  7 A. No.  8 <b>Q. Let's go to page 20 now.</b>  9 A. Now, I have the mark coming  10 through. Should I use a pen?  11 <b>Q. We'll do that next time, we'll</b>  12 <b>take that away.</b>  13 <b>Now on page 20, again, this is an image</b>  14 <b>from the consolidated cases?</b>  15 A. That's correct.  16 <b>Q. And as you look in the top on 1b,</b>  17 <b>you see blue. And that is polypropylene mesh.</b>  18 A. Yeah, that's a cross-section of a  19 blue polypropylene fiber.  20 <b>Q. And it looks like it's been folded</b>  21 <b>as a part of the microtoming process; is that fair?</b>  22 A. It's not microtoming process; it  23 folds, curls. Polypropylene just tends to curl.  24 <b>Q. But this is a four-micron thick</b>  25 <b>slice of polypropylene, correct?</b></p>

27 (Pages 102 to 105)

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<p>1 A. Then it curls up like this. Some</p> <p>2 of them just stay flat. Some of them curl up.</p> <p>3 <b>Q. But this is an artifact of the</b></p> <p>4 <b>sample preparation process?</b></p> <p>5 A. Curling? Yes.</p> <p>6 <b>Q. So the curling of the blue</b></p> <p>7 <b>polypropylene in set 1b on page 20 is an artifact</b></p> <p>8 <b>of the sample preparation process?</b></p> <p>9 A. That's correct.</p> <p>10 <b>Q. All right?</b></p> <p>11 A. The exact shape of that slice is</p> <p>12 better to be estimated by the tissue which</p> <p>13 surrounds it because tissue didn't curl, didn't</p> <p>14 move much. There is more movement of the</p> <p>15 polypropylene slices.</p> <p>16 <b>Q. What does that mean? I don't</b></p> <p>17 <b>understand.</b></p> <p>18 A. Well, see, when the tissue is cut</p> <p>19 it doesn't curl, it doesn't wrinkle most of the</p> <p>20 time because of the technology of the slides and</p> <p>21 knives. Everything was designed to keep it flat.</p> <p>22 So over the years, over the hundred</p> <p>23 years we learned how to keep it flat. With</p> <p>24 polypropylene, because it is a different material,</p> <p>25 doesn't stick. The histological slides don't hold</p>	<p>1 <b>slide comes from the set of 22 patients that you</b></p> <p>2 <b>received from Dr. Kreutzer?</b></p> <p>3 MR. ORENT: Objection.</p> <p>4 THE WITNESS: My recollection is it was</p> <p>5 later, one of the later cases.</p> <p>6 BY MR. THOMAS:</p> <p>7 <b>Q. Do you know which one it is?</b></p> <p>8 A. I can probably trace it but...</p> <p>9 <b>Q. Is it a medical-legal case?</b></p> <p>10 A. I think so, but again it would be</p> <p>11 hard for me -- just what I recall, it is a TVT that</p> <p>12 I kept track quite well, TVT or TVT-O.</p> <p>13 <b>Q. If I asked you to, could you tell</b></p> <p>14 <b>me where it came from?</b></p> <p>15 A. I can make an effort to figure it</p> <p>16 out.</p> <p>17 <b>Q. Okay.</b></p> <p>18 A. If I can't, I can't.</p> <p>19 <b>Q. I'm going to want to know where</b></p> <p>20 <b>all these came from. That's what we asked for in</b></p> <p>21 <b>advance and I understand we don't have it today?</b></p> <p>22 A. I never had the purpose to trace</p> <p>23 individual cases unless it's for a specific -- the</p> <p>24 report is prepared for a specific patient.</p> <p>25 <b>Q. Okay.</b></p>
Page 107	Page 109
<p>1 it as well so it's not firmly attached.</p> <p>2 So, when it's cut initially, it may</p> <p>3 stay flat. But then after drying and some chemical</p> <p>4 treatment, starts curling up, while tissue stays</p> <p>5 flat.</p> <p>6 <b>Q. Okay.</b></p> <p>7 A. Curling up or moving, I mean curls</p> <p>8 up, lifts up, and then starts floating around.</p> <p>9 <b>Q. What are you going to say at trial</b></p> <p>10 <b>about Figure Set 1b on page 20?</b></p> <p>11 A. Just an example of foreign body</p> <p>12 type inflammatory reaction.</p> <p>13 <b>Q. Okay. Let's go to page 21.</b></p> <p>14 A. Yes.</p> <p>15 <b>Q. Page 21 is Figure Set 1c:</b></p> <p>16 <b>"Foreign body inflammatory</b></p> <p>17 <b>reaction, H&amp;E 40X, image of</b></p> <p>18 <b>additional TVT cases."</b></p> <p>19 <b>Now, I think you told us before that</b></p> <p>20 <b>these are previous TVT and TVT-O cases?</b></p> <p>21 A. Yes.</p> <p>22 <b>Q. Do you know whether this is a TVT</b></p> <p>23 <b>or a TVT-O?</b></p> <p>24 A. No.</p> <p>25 <b>Q. Can you tell me today whether this</b></p>	<p>1 A. Because of it wasn't my purpose.</p> <p>2 My purpose was to collect information and</p> <p>3 photographs for TVT or TVT-O as device. That's why</p> <p>4 I have difficulty tracing all of them back. Some</p> <p>5 of them can be traced; some of them cannot.</p> <p>6 <b>Q. If you look at Figure Set 1c, top</b></p> <p>7 <b>left, again, you see the blue polypropylene,</b></p> <p>8 <b>correct?</b></p> <p>9 A. Yes, I do. And the other hole</p> <p>10 above it may still contain polypropylene but it's</p> <p>11 clear because the way it's done two fibers are</p> <p>12 combined together.</p> <p>13 One filament is blue, one filament is</p> <p>14 clear. And they go through the knitting product</p> <p>15 together, this pair.</p> <p>16 <b>Q. Does the fact that the hole that</b></p> <p>17 <b>you just identified above the presence of blue</b></p> <p>18 <b>polypropylene has an irregular shape, does that</b></p> <p>19 <b>impact your opinion as to whether the polypropylene</b></p> <p>20 <b>is present or not?</b></p> <p>21 A. Not irregular. It's more regular</p> <p>22 curvilinear shape, and there is inflammation around</p> <p>23 it, so there are several features which tell me</p> <p>24 that this is space where polypropylene either still</p> <p>25 is or used to be.</p>

28 (Pages 106 to 109)

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<p style="text-align: right;">Page 110</p> <p>1 If I had polarized light or if I had</p> <p>2 microscope right now and it would be in the</p> <p>3 microscope, I could flip polarized light and see.</p> <p>4 <b>Q. Now, is that tissue that is in</b></p> <p>5 <b>that large white area above the polypropylene?</b></p> <p>6 A. It is a small fragment of tissue.</p> <p>7 <b>Q. Is that part of a microtoming</b></p> <p>8 <b>artifact?</b></p> <p>9 MR. ORENT: Objection.</p> <p>10 THE WITNESS: Microtomy or processing,</p> <p>11 it's hard to say, but it's an artifact. It's</p> <p>12 displaced.</p> <p>13 BY MR. THOMAS:</p> <p>14 <b>Q. As you look down to the piece of</b></p> <p>15 <b>polypropylene in set 1c, on the top of that blue</b></p> <p>16 <b>portion it appears to be some tissue?</b></p> <p>17 A. Yes.</p> <p>18 <b>Q. And that tissue looks to fit right</b></p> <p>19 <b>into the tissue above it?</b></p> <p>20 A. That's correct.</p> <p>21 <b>Q. So that's pulled away from the</b></p> <p>22 <b>tissue as a part of the microtoming process,</b></p> <p>23 <b>correct?</b></p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: You have good eyes.</p>	<p style="text-align: right;">Page 112</p> <p>1 A. Yes, sometimes I do that.</p> <p>2 <b>Q. Okay. Anything else remarkable</b></p> <p>3 <b>about the figures on page 21?</b></p> <p>4 A. No.</p> <p>5 <b>Q. Let's go to page 22, Figure Set</b></p> <p>6 <b>2a. Again, this is images of additional TVT cases.</b></p> <p>7 <b>And these would be cases that were not part of the</b></p> <p>8 <b>consolidated group that you've just reviewed,</b></p> <p>9 <b>correct?</b></p> <p>10 A. That is correct.</p> <p>11 <b>Q. And can you tell me by looking at</b></p> <p>12 <b>this whether it was part of the set of cases that</b></p> <p>13 <b>you received from Dr. Kreutzer?</b></p> <p>14 A. No, that was later case.</p> <p>15 <b>Q. How can you tell me that? How do</b></p> <p>16 <b>you know that?</b></p> <p>17 A. Quality of the picture. I see it</p> <p>18 was not taken with the camera that I had at the</p> <p>19 time that I received the, those specimens.</p> <p>20 <b>Q. Was this taken from an active</b></p> <p>21 <b>medical-legal case involving Ethicon?</b></p> <p>22 MR. ORENT: Objection to the form.</p> <p>23 THE WITNESS: I don't remember. Most</p> <p>24 likely it is.</p> <p>25</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MR. THOMAS:</p> <p>2 <b>Q. Why don't I see any bark on that</b></p> <p>3 <b>polypropylene?</b></p> <p>4 A. Two reasons. Not enough</p> <p>5 resolution of the picture, and second, not in</p> <p>6 focus.</p> <p>7 <b>Q. And do you know how long this mesh</b></p> <p>8 <b>was implanted in the person?</b></p> <p>9 A. No, I don't remember.</p> <p>10 <b>Q. But you have those records?</b></p> <p>11 A. Most likely. But again, some</p> <p>12 patient samples came without much records. Most of</p> <p>13 the samples I received had implantation dates.</p> <p>14 <b>Q. So what is remarkable about the</b></p> <p>15 <b>slides in Figure Set 1c which you'll talk to the</b></p> <p>16 <b>jury about?</b></p> <p>17 A. It shows a blue fiber. It shows</p> <p>18 that some of the fibers are blue, but otherwise it</p> <p>19 shows exactly the same feature as before.</p> <p>20 It's kind of onion skin mesh fiber</p> <p>21 covered by inflammation, and then outside of that</p> <p>22 everything is encapsulated in scar tissue.</p> <p>23 <b>Q. And the scar tissue would be</b></p> <p>24 <b>reflected in your notations in the ones on the</b></p> <p>25 <b>right?</b></p>	<p style="text-align: right;">Page 113</p> <p>1 BY MR. THOMAS:</p> <p>2 <b>Q. But you can't tell me today what</b></p> <p>3 <b>it might be?</b></p> <p>4 A. It's hard to say.</p> <p>5 <b>Q. And what is remarkable about the</b></p> <p>6 <b>image in Figure Set 2a on page 22 for purposes of</b></p> <p>7 <b>the jury?</b></p> <p>8 A. Can I have a pen?</p> <p>9 <b>Q. I'll give you a blue pen.</b></p> <p>10 A. Remember, earlier you asked me</p> <p>11 about why you cannot see bark? Now you can see the</p> <p>12 bark, so this is the bark. Right there.</p> <p>13 <b>Q. What you've indicated is on the</b></p> <p>14 <b>left?</b></p> <p>15 A. This is the bark right there.</p> <p>16 This is the bark right there.</p> <p>17 <b>Q. Now are you assuming for purposes</b></p> <p>18 <b>of that statement that polypropylene is still</b></p> <p>19 <b>present in that slide?</b></p> <p>20 A. Well, degraded part of the</p> <p>21 polypropylene is still present for sure, because I</p> <p>22 can see it stained. If the core remains unlocked,</p> <p>23 there's a different question. In this area, most</p> <p>24 likely it is.</p> <p>25 <b>Q. You say most likely it is?</b></p>

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<p style="text-align: right;">Page 114</p> <p>1 A. Because this bark layer is free in 2 the space, and doesn't happen that often. Because 3 if it was free in this area, it would flow all the 4 way. So the way it remains in the tissue it 5 remains attached to tissue. 6 So the bark which is firmly attached to 7 tissue like in this area is most likely detached. 8 So there is no fiber core in this area. But in 9 this specific area, I suspect the core of the fiber 10 is still there. 11 <b>Q. Let me do something so the record</b> 12 <b>is clear.</b> 13 <b>You've made some arrows on Figure 2 A,</b> 14 <b>on the upper image, and there's two arrows on the</b> 15 <b>upper left-hand portion and you suggest that</b> 16 <b>indicates bark -- you suggest that indicates bark,</b> 17 <b>correct?</b> 18 A. I didn't suggest. I just pointed 19 where it is. 20 <b>Q. Okay, fine. And then down in the</b> 21 <b>lower right-hand corner, you've drawn several</b> 22 <b>diagonal lines in addition to two arrows.</b> 23 <b>The two arrows indicate bark, as you</b> 24 <b>understand it, and you believe that the diagonal</b> 25 <b>lines represent polypropylene which is present in</b></p>	<p style="text-align: right;">Page 116</p> <p>1 case, you have the report. 2 BY MR. THOMAS: 3 <b>Q. Are you familiar with whole slide</b> 4 <b>imaging?</b> 5 A. Yes, I am. 6 <b>Q. Do you do whole slide imaging of</b> 7 <b>these cases?</b> 8 A. Yes, I do. 9 <b>Q. So you have --</b> 10 A. Not for all of them. For some 11 cases, especially the later ones. 12 <b>Q. Okay. And who maintains your</b> 13 <b>whole slide imaging equipment; who has that? St.</b> 14 <b>Michael's?</b> 15 A. Yes, St. Michael's. It's standard 16 equipment. 17 <b>Q. Do you have to pay St. Michael's</b> 18 <b>for use of the whole slide imaging equipment?</b> 19 A. No. 20 <b>Q. Okay.</b> 21 A. It's free for researchers. 22 <b>Q. What kind of machine do they have?</b> 23 A. Aperio. 24 <b>Q. So, you could supply to us digital</b> 25 <b>images of the slides that you have on whole slide</b></p>
<p style="text-align: right;">Page 115</p> <p>1 <b>the slide, correct?</b> 2 A. Most likely. 3 <b>Q. Okay. Now, we requested that all</b> 4 <b>of the slides that were used in your report be</b> 5 <b>forwarded to our pathologist for their review.</b> 6 <b>Was this slide forwarded to them, to</b> 7 <b>your knowledge?</b> 8 MR. ORENT: Objection. 9 THE WITNESS: No, it's an additional 10 case. 11 BY MR. THOMAS: 12 <b>Q. Okay.</b> 13 MR. ORENT: By the way, just for the 14 record, we have not received any slides from your 15 pathologist either and we have requested that 16 repeatedly. 17 MR. THOMAS: We don't have any to give 18 you. We're working from the same set of slides. 19 MR. ORENT: So you're using the 20 plaintiff's stained slides -- 21 MR. THOMAS: So far we have. We figure 22 it's better off using one set of slides. And to 23 the extent we make any, you will have them 24 promptly. 25 THE WITNESS: If it was a litigation</p>	<p style="text-align: right;">Page 117</p> <p>1 <b>imaging, correct?</b> 2 A. As long as you're entitled to 3 receive material or information about the case. 4 <b>Q. Okay. What else is remarkable</b> 5 <b>about Figure Set 2a on page 22?</b> 6 A. Oh, it is a very nice example, 7 again of this layering, onion skinning. 8 The mesh fibers are surrounded by halo 9 of foreign body reaction and everything is encased 10 in solid scar plate. 11 And then normal tissue is beyond the 12 solid scar plate so it is a good example of how it 13 happens. 14 <b>Q. And in terms of -- you've told me</b> 15 <b>that on the upper left of the area where you had</b> 16 <b>the arrows, there's likely not polypropylene but in</b> 17 <b>the lower right there likely is polypropylene?</b> 18 A. Yes. 19 <b>Q. How about in the white area to the</b> 20 <b>right where you've written; can you tell whether</b> 21 <b>polypropylene is present or not?</b> 22 A. Not without polarized light. 23 MR. ORENT: Counsel, we've been going 24 about another hour. Shall we take a short break? 25 MR. THOMAS: Good time, yes.</p>

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<p style="text-align: right;">Page 118</p> <p>1 -- RECESS AT 11:27 --</p> <p>2 -- UPON RESUMING AT 11:44 --</p> <p>3 BY MR. THOMAS:</p> <p>4 <b>Q. Doctor, going back to image 2a on</b></p> <p>5 <b>page 22 of your report, you described this scar</b></p> <p>6 <b>area in your testimony, and then showed how the</b></p> <p>7 <b>scar then changed to normal tissue, correct?</b></p> <p>8 A. That' is correct.</p> <p>9 <b>Q. How thick is the area between what</b></p> <p>10 <b>you show to be the polypropylene mesh and the scar</b></p> <p>11 <b>to the normal tissue? How thick is that area</b></p> <p>12 <b>between the polypropylene and the normal tissue?</b></p> <p>13 A. You mean in this specific image or</p> <p>14 in general?</p> <p>15 <b>Q. In this image.</b></p> <p>16 A. It depends on which part of the</p> <p>17 mesh. The thinnest part is within the hundred</p> <p>18 microns. The thickest part can be as thick as</p> <p>19 couple of millimeters, if we measure the whole</p> <p>20 thing like this.</p> <p>21 <b>Q. And just for the record, when you</b></p> <p>22 <b>say within a hundred microns, you're referring to</b></p> <p>23 <b>the area on the left side of the lower image in the</b></p> <p>24 <b>yellow, through the scar to the normal tissue. And</b></p> <p>25 <b>when you're referring to the couple of millimeters,</b></p>	<p style="text-align: right;">Page 120</p> <p>1 <b>Where does this come from?</b></p> <p>2 A. It came from, if I remember</p> <p>3 correctly, Edwards case. If I remember correctly.</p> <p>4 <b>Q. What is it about this that makes</b></p> <p>5 <b>you think it's the Edwards case?</b></p> <p>6 A. It is an old photograph.</p> <p>7 <b>Q. And in the top, on the right-hand</b></p> <p>8 <b>side of the image, it looks like a piece of blue</b></p> <p>9 <b>polypropylene that's displaced in its location; is</b></p> <p>10 <b>that fair?</b></p> <p>11 A. Slightly displaced, most of it</p> <p>12 sits right there, it was in vivo.</p> <p>13 <b>Q. The other blue pieces that appear</b></p> <p>14 <b>there other than the -- why don't you just mark</b></p> <p>15 <b>that with an "X" for me so it's clear what we're</b></p> <p>16 <b>talking about.</b></p> <p>17 A. (Witness complies).</p> <p>18 <b>Q. There are other blue pieces</b></p> <p>19 <b>throughout that image, is that polypropylene or is</b></p> <p>20 <b>that stain?</b></p> <p>21 A. You mean the blue areas here?</p> <p>22 <b>Q. Yes.</b></p> <p>23 A. Some of it is probably displaced</p> <p>24 polypropylene, it's hard to say because of the</p> <p>25 resolution. It could just be inflammation because</p>
<p style="text-align: right;">Page 119</p> <p>1 <b>you were referring to normal tissue to normal</b></p> <p>2 <b>tissue in between the two mesh fibers; is that</b></p> <p>3 <b>fair?</b></p> <p>4 MR. ORENT: Objection.</p> <p>5 THE WITNESS: That's correct.</p> <p>6 BY MR. THOMAS:</p> <p>7 <b>Q. And similarly, down below on the</b></p> <p>8 <b>lower left, where you show the polypropylene mesh,</b></p> <p>9 <b>you show scar and then you do show normal tissue;</b></p> <p>10 <b>how far is it from the polypropylene to the normal</b></p> <p>11 <b>tissue; how wide is the scar band?</b></p> <p>12 A. The same, within 100 microns.</p> <p>13 Sometimes you have normal tissue pushing into the</p> <p>14 pores, sometimes not. Sometimes the scar plate is</p> <p>15 within a hundred microns -- I mean, the scar</p> <p>16 capsule. Sometimes it goes to the millimeters,</p> <p>17 three, four millimeters, it depends.</p> <p>18 <b>Q. Okay. Anything else remarkable</b></p> <p>19 <b>about the images on page 22?</b></p> <p>20 A. No, we discussed everything, I</p> <p>21 think.</p> <p>22 MR. ORENT: Objection.</p> <p>23 BY MR. THOMAS:</p> <p>24 <b>Q. Let's go to page 23 please, Figure</b></p> <p>25 <b>Set 2b. Let's talk about this a little bit.</b></p>	<p style="text-align: right;">Page 121</p> <p>1 there is a weird color coming into the pictures.</p> <p>2 <b>Q. If the blue that appears there is</b></p> <p>3 <b>in fact displaced polypropylene, then that's part</b></p> <p>4 <b>of the microtoming artifact; is that fair?</b></p> <p>5 A. Yes, that's fair.</p> <p>6 <b>Q. All right.</b></p> <p>7 A. Anywhere where cross-section of</p> <p>8 the fiber overlaps with tissue, is a displacement.</p> <p>9 <b>Q. All right. And you title this,</b></p> <p>10 <b>"Fibrous Bridging and Scar Encapsulation". And</b></p> <p>11 <b>it's four times power. What does this show?</b></p> <p>12 A. All pores in this section of the</p> <p>13 mesh are filled with scar tissue. So normal tissue</p> <p>14 is beyond the scar plate, and all the pores are in</p> <p>15 the spaces in between, and mesh walls are filled</p> <p>16 with scar tissue.</p> <p>17 <b>Q. Okay. The magnification of the</b></p> <p>18 <b>image on the prior page is five times this</b></p> <p>19 <b>magnification, correct?</b></p> <p>20 A. About, yes.</p> <p>21 <b>Q. Okay. And can you tell me by</b></p> <p>22 <b>looking at the image on page 23 in the cluster of</b></p> <p>23 <b>four circles, how close it is from the</b></p> <p>24 <b>polypropylene across the scar tissue to the normal</b></p> <p>25 <b>tissue?</b></p>

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<p>1 A. In this area?</p> <p>2 <b>Q. Yes.</b></p> <p>3 A. It would be within the 100 microns</p> <p>4 or so.</p> <p>5 <b>Q. Mark that -- good.</b></p> <p>6 A. (Witness complies).</p> <p>7 In this case, it's thicker, could be as</p> <p>8 thick as 200 microns.</p> <p>9 <b>Q. Okay.</b></p> <p>10 A. It could be .2 millimeters,</p> <p>11 roughly.</p> <p>12 <b>Q. If you wanted to measure that on</b></p> <p>13 <b>the slides that you have, can that be done?</b></p> <p>14 A. With a eyepiece micrometer, yes.</p> <p>15 <b>Q. Anything else remarkable about</b></p> <p>16 <b>Figure 2b other than showing the scar?</b></p> <p>17 A. Fiber bridging, and completely</p> <p>18 encapsulating the entire structure of mesh pores</p> <p>19 that fill the scar tissue, and normal tissue is</p> <p>20 outside. This is the mesh scar complex, or mesh</p> <p>21 scar plate.</p> <p>22 <b>Q. As you look at this image, is this</b></p> <p>23 <b>a complete slide?</b></p> <p>24 A. No, there is tissue beyond</p> <p>25 slightly. And this end, I think is here on the</p>	<p>1 <b>the Edwards case, your best recollection?</b></p> <p>2 A. Yes.</p> <p>3 <b>Q. And it's magnified ten times, and</b></p> <p>4 <b>this is the one that is a magnification of the far</b></p> <p>5 <b>right side of the image on page 23?</b></p> <p>6 A. Likely at different level.</p> <p>7 <b>Q. What do you mean, a different</b></p> <p>8 <b>slide?</b></p> <p>9 A. Different slide, yes.</p> <p>10 <b>Q. Okay.</b></p> <p>11 A. So it's the same piece, but cut</p> <p>12 little deeper.</p> <p>13 <b>Q. Now if you look on the top page of</b></p> <p>14 <b>page 24, top image, on the right side there's a</b></p> <p>15 <b>blue, that's again, displaced polypropylene?</b></p> <p>16 A. Yes, this is displaced</p> <p>17 polypropylene. And this as well (indicating).</p> <p>18 <b>Q. Okay. And that's an artifact due</b></p> <p>19 <b>to the microtoming process?</b></p> <p>20 A. It could've done that, yes.</p> <p>21 <b>Q. And the description down below</b></p> <p>22 <b>again is "fibrous bridging and scar encapsulation",</b></p> <p>23 <b>does this image show anything in addition to what</b></p> <p>24 <b>we've talked about in the prior slides?</b></p> <p>25 A. This is a terminal pore.</p>
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<p>1 next page, page 24.</p> <p>2 <b>Q. Okay. We'll come to that in a</b></p> <p>3 <b>second.</b></p> <p>4 A. That's my recollection.</p> <p>5 <b>Q. The figure on 2a, page 22, is</b></p> <p>6 <b>obviously a smaller part of a bigger slide, correct?</b></p> <p>7 A. That's correct.</p> <p>8 <b>Q. And you believe that the image on</b></p> <p>9 <b>page 23 is also a smaller part of a bigger slide?</b></p> <p>10 A. I think most of the mesh is here</p> <p>11 on the slide --</p> <p>12 <b>Q. Um-hum.</b></p> <p>13 A. -- so there's not much mesh</p> <p>14 beyond.</p> <p>15 <b>Q. That's why I'm asking the</b></p> <p>16 <b>question.</b></p> <p>17 <b>Does the image that's shown on page 23</b></p> <p>18 <b>represent the outer boundaries of the mesh in that</b></p> <p>19 <b>slide?</b></p> <p>20 A. I think so.</p> <p>21 <b>Q. Okay.</b></p> <p>22 A. I think so, there's an edge of</p> <p>23 tissue here. Now, this exactly piece of this --</p> <p>24 <b>Q. You've now turned the page, you're</b></p> <p>25 <b>on page 24. So you believe this is probably from</b></p>	<p>1 <b>Q. Sorry?</b></p> <p>2 A. This is a terminal pore of the</p> <p>3 mesh. So this is the edge of the mesh and the</p> <p>4 terminal pore contains normal non-scar tissue.</p> <p>5 <b>Q. When you say "terminal pore"</b></p> <p>6 <b>that's the outside pore?</b></p> <p>7 A. Yes, it is.</p> <p>8 <b>Q. So what is the significance of the</b></p> <p>9 <b>terminal pore having normal tissue?</b></p> <p>10 A. It just shows comparison. Pores</p> <p>11 which are not filled with scar tissue, and pores</p> <p>12 which are filled with scar tissue. So this</p> <p>13 specific pore contained normal scar tissue. So</p> <p>14 within that specific pore, there's no fibrous</p> <p>15 bridging.</p> <p>16 <b>Q. Is it fair to say every place we</b></p> <p>17 <b>see the blue, we see displaced polypropylene?</b></p> <p>18 A. Most of the time. It can be just</p> <p>19 a weird color of inflammation.</p> <p>20 <b>Q. Okay. Anything else remarkable</b></p> <p>21 <b>about the slide on page 24?</b></p> <p>22 A. No.</p> <p>23 <b>Q. Okay. Let's go to page 25.</b></p> <p>24 A. Yes.</p> <p>25 <b>Q. This is cited to an article. Do</b></p>

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<p style="text-align: right;">Page 126</p> <p>1 you know off the top of your head what article that</p> <p>2 is?</p> <p>3 A. On the safety of synthetic sling</p> <p>4 surgery, I believe.</p> <p>5 <b>Q. Are you able to tell me what slide</b></p> <p>6 <b>that is, what plaintiff? Strike that.</b></p> <p>7 <b>Is that a medical-legal slide?</b></p> <p>8 A. The picture comes from the same</p> <p>9 case, as you can see it's exactly the same.</p> <p>10 <b>Q. Okay. Is B part of A?</b></p> <p>11 A. No, I don't believe so.</p> <p>12 <b>Q. Let's talk about A. And what does</b></p> <p>13 <b>the "BF" mean?</b></p> <p>14 A. "Bridging fibrosis".</p> <p>15 <b>Q. And the "AT"?</b></p> <p>16 <b>"Adipose tissue"?</b></p> <p>17 A. Adipose tissue, yes.</p> <p>18 <b>Q. What is the significance of the</b></p> <p>19 <b>adipose tissue?</b></p> <p>20 A. It's a normal non-scar tissue.</p> <p>21 <b>Q. So what is the significance of</b></p> <p>22 <b>including this slide in your report if it's the</b></p> <p>23 <b>same thing that you had in the prior two slides?</b></p> <p>24 A. It's a little bit different.</p> <p>25 Because, see, on the bottom, B, it shows scar</p>	<p style="text-align: right;">Page 128</p> <p>1 me the magnification of that image?</p> <p>2 A. Close to times four maybe --</p> <p>3 because there's cropping and then the size was --</p> <p>4 now it's hard to -- it's much larger than it</p> <p>5 appears in the publication. So I would say for</p> <p>6 this specific, it would be close to times four</p> <p>7 objective.</p> <p>8 <b>Q. If you go down here it says:</b></p> <p>9 <b>"Scar encapsulating mesh in</b></p> <p>10 <b>surrounding pre-existent normal</b></p> <p>11 <b>adipose tissue and muscle tissues, a</b></p> <p>12 <b>2.5 image of histological sections."</b></p> <p>13 <b>That means it's magnified 2.5 times.</b></p> <p>14 A. It means that the objective you</p> <p>15 would use to produce this appearance in the</p> <p>16 microscope, this would be times 2.5.</p> <p>17 <b>Q. Okay. But the degree of</b></p> <p>18 <b>magnification is different from that?</b></p> <p>19 A. On this page?</p> <p>20 <b>Q. Yes.</b></p> <p>21 A. Yes. Because it's cropped and</p> <p>22 resized and the publication is much smaller.</p> <p>23 <b>Q. I see.</b></p> <p>24 A. So if you trace it, if more</p> <p>25 correctly to trace it, to trace is the objective,</p>
<p style="text-align: right;">Page 127</p> <p>1 tissue in a different stain.</p> <p>2 Scar tissue may have some smooth</p> <p>3 muscle, when the scar tissue is being remodeled by</p> <p>4 myofibroblast. Myofibroblast can have smooth</p> <p>5 muscle. But once it's mature scar tissue, there is</p> <p>6 no contractile filament in the cells anymore, and</p> <p>7 it doesn't stain with smooth muscles stain.</p> <p>8 But, normal tissue of vaginal wall</p> <p>9 contains smooth muscle. So here you can see that</p> <p>10 the fibers bridging, can be separated from normal</p> <p>11 tissue by using smooth muscle stain.</p> <p>12 <b>Q. And so the smooth muscle, or the</b></p> <p>13 <b>normal tissue is represented by the brown?</b></p> <p>14 A. Yes.</p> <p>15 <b>Q. And this is another representation</b></p> <p>16 <b>of the fibrous bridging and scar encapsulations</b></p> <p>17 <b>depicted in blue?</b></p> <p>18 A. Yes.</p> <p>19 <b>Q. Is that the only significance of</b></p> <p>20 <b>that stain?</b></p> <p>21 A. Yes.</p> <p>22 <b>Q. Okay.</b></p> <p>23 A. For this specific picture, yes, it</p> <p>24 is.</p> <p>25 <b>Q. All right. Are you able to tell</b></p>	<p style="text-align: right;">Page 129</p> <p>1 you would use to see like this in the microscope.</p> <p>2 <b>Q. And you could use the optical</b></p> <p>3 <b>micrometer in order to measure to the extent</b></p> <p>4 <b>necessary?</b></p> <p>5 A. Yes, I can.</p> <p>6 <b>Q. Anything else about this image?</b></p> <p>7 A. No.</p> <p>8 <b>Q. Let's go to page 26, image 3a.</b></p> <p>9 A. Yes.</p> <p>10 <b>Q. What's the purpose of this image?</b></p> <p>11 A. This image shows the nerve in H&amp;E</p> <p>12 stain.</p> <p>13 <b>Q. What is the significance of</b></p> <p>14 <b>showing the nerve; just the fact that you can show</b></p> <p>15 <b>it? Is there any damage to it or any issues</b></p> <p>16 <b>associated with it?</b></p> <p>17 A. It's normal nerve, it's present</p> <p>18 within this mesh scar plate, it innervates the</p> <p>19 tissue which is inside and outside of the mesh. It</p> <p>20 can become trapped.</p> <p>21 <b>Q. Is it trapped in this image?</b></p> <p>22 A. Well, it is in scar tissue. So</p> <p>23 it's trapped in scar tissue.</p> <p>24 <b>Q. Is there any indication that this</b></p> <p>25 <b>nerve is damaged in this image?</b></p>

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<p>1 A. Not from this power, I don't see</p> <p>2 any -- "damage", you mean atrophic degenerated or</p> <p>3 damaged in terms of physical damage?</p> <p>4 <b>Q. Any kind of damage.</b></p> <p>5 A. It is in scar tissue. For a nerve</p> <p>6 to be in scar tissue, is not a healthy environment.</p> <p>7 <b>Q. But not all nerves in scar tissue</b></p> <p>8 <b>produce symptoms, correct?</b></p> <p>9 A. Not all.</p> <p>10 <b>Q. And you can't tell by looking at</b></p> <p>11 <b>this image, whether the nerve in Figure Set 3a is</b></p> <p>12 <b>producing any symptoms, correct?</b></p> <p>13 A. Again, it depends on timing. It</p> <p>14 may produce symptoms at one time and not produce at</p> <p>15 another time.</p> <p>16 If this specific nerve was producing</p> <p>17 pain sensation, it would be difficult to determine.</p> <p>18 <b>Q. But you can't tell, looking at the</b></p> <p>19 <b>nerve in Figure Set 3a, whether that nerve is</b></p> <p>20 <b>producing symptoms for this patient, correct?</b></p> <p>21 A. I can tell you that this nerve is</p> <p>22 in a situation when it can produce symptom. This</p> <p>23 is the main thing I can say, it can because it is</p> <p>24 in an abnormal environment.</p> <p>25 <b>Q. And the abnormal environment is</b></p>	<p>1 A. It's a mixed nerve.</p> <p>2 <b>Q. What do you mean by "mixed nerve"?</b></p> <p>3 A. "Mixed" means they're both</p> <p>4 afferent and efferent, or motor and sensory signals</p> <p>5 going back and forth.</p> <p>6 <b>Q. How can you tell it does both? Do</b></p> <p>7 <b>all nerves do both?</b></p> <p>8 A. Peripheral nerves, yes.</p> <p>9 <b>Q. All of them?</b></p> <p>10 A. Except for head.</p> <p>11 <b>Q. Okay. So are all nerves in the</b></p> <p>12 <b>body, peripheral nerves, capable of mediating pain?</b></p> <p>13 A. Except for cranial nerves.</p> <p>14 <b>Q. Okay. And what's the basis for</b></p> <p>15 <b>your understanding in that regard?</b></p> <p>16 A. It's a basic knowledge, it's in</p> <p>17 the textbooks.</p> <p>18 <b>Q. Okay.</b></p> <p>19 A. There is some very small</p> <p>20 proportion of nerves, peripheral nerves, less than</p> <p>21 5 percent, which are only sensory. So some of the</p> <p>22 nerves will be only sensory. But there are almost</p> <p>23 no, only motor nerves outside of the cranial</p> <p>24 nerves.</p> <p>25 <b>Q. Can you, by light microscopy,</b></p>
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<p>1 <b>the presence in the scar tissue?</b></p> <p>2 A. Yes. In addition to be present</p> <p>3 inside the mesh.</p> <p>4 <b>Q. Okay. Well, it's adjacent to the</b></p> <p>5 <b>mesh, correct?</b></p> <p>6 A. I don't know. There might be</p> <p>7 fiber right there.</p> <p>8 <b>Q. Okay.</b></p> <p>9 A. So it can be inside or outside, it</p> <p>10 doesn't matter. It's in scar tissue, it's abnormal</p> <p>11 environment, it can produce mesh. And we know that</p> <p>12 traumatic neuromas, which is the formation of a</p> <p>13 mesh in scar tissue, is a painful lesion. This is</p> <p>14 an established fact.</p> <p>15 <b>Q. But there's no traumatic neuroma</b></p> <p>16 <b>in this image, correct?</b></p> <p>17 A. A mesh is deformed, we can see</p> <p>18 it's getting there.</p> <p>19 <b>Q. Can you see a traumatic neuroma in</b></p> <p>20 <b>this image, 3a on page 26?</b></p> <p>21 A. The formation is not significant</p> <p>22 to call it a traumatic neuroma. So in this</p> <p>23 specific image, I would not use that term.</p> <p>24 <b>Q. Now, can you tell whether the</b></p> <p>25 <b>nerve on page 26 that you show is a motor nerve?</b></p>	<p>1 <b>distinguish among the type of nerves which you see?</b></p> <p>2 A. What do you mean, what type of</p> <p>3 nerves?</p> <p>4 <b>Q. Well, sensory and motor nerves?</b></p> <p>5 A. We just agreed that they're all</p> <p>6 mixed.</p> <p>7 <b>Q. You said that, okay.</b></p> <p>8 <b>Is there any way for you to distinguish</b></p> <p>9 <b>by light microscopy which nerves are capable of</b></p> <p>10 <b>mediating pain?</b></p> <p>11 A. They all are.</p> <p>12 <b>Q. Okay. 5 percent you said, where</b></p> <p>13 <b>are they?</b></p> <p>14 A. 5 percent is still sensory. So</p> <p>15 all of them can deliver pain. Some of them,</p> <p>16 5 percent, may not be able to do any motor</p> <p>17 function, but they will still be able to transmit</p> <p>18 pain. And it also depends on the size, because</p> <p>19 once you go into the very small branches, they</p> <p>20 become more specialized. If you go into the large</p> <p>21 trunk, then you get all of them mixed together.</p> <p>22 <b>Q. When you talk about going into the</b></p> <p>23 <b>nerve twigs, that's what you're talking about,</b></p> <p>24 <b>right?</b></p> <p>25 A. Fibers, individual fibers, yes.</p>

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<p style="text-align: right;">Page 134</p> <p>1 <b>Q. Then they become more specialized;</b>  2 <b>what do you mean by that?</b>  3 A. So they may have more function for  4 sensory or motor function.  5 <b>Q. So as the nerves break into twigs,</b>  6 <b>will there be some nerves that don't mediate pain,</b>  7 <b>or they still mediate pain?</b>  8 A. Fibers. If you go into fibers  9 which is even smaller than twigs, which is  10 individual axon, those will have individual  11 function.  12 <b>Q. And what are we looking at nerves</b>  13 <b>here; are we looking at twigs, fibers, or are we</b>  14 <b>looking at nerves?</b>  15 A. It's a nerve. It's thicker than a  16 twig.  17 <b>Q. Okay. And what is remarkable</b>  18 <b>about what you see in Figure 3a; anything more than</b>  19 <b>you've just described, the presence of a nerve</b>  20 <b>adjacent to mesh?</b>  21 A. No, just everything else -- we  22 discussed everything significant.  23 <b>Q. Now, the polypropylene in the</b>  24 <b>lower left-hand corner image, that's blue</b>  25 <b>polypropylene, correct?</b></p>	<p style="text-align: right;">Page 136</p> <p>1 A. Yes. For this specific image,  2 about 20 times -- 20 times objective magnification.  3 The magnification itself is higher,  4 because there's also an eyepiece, but eyepiece is  5 fixed.  6 <b>Q. Look at the right side of that</b>  7 <b>image with the polypropylene. It's folded over, on</b>  8 <b>the right side; you'd agree with me there is no</b>  9 <b>bark?</b>  10 A. Not visible bark.  11 <b>Q. Okay. If we go to page 27, set</b>  12 <b>3b.</b>  13 <b>So 3a comes from the images from the</b>  14 <b>consolidated cases, correct?</b>  15 A. That is correct.  16 <b>Q. So we should have this slide, I</b>  17 <b>think. So paragraph 3b, so set 3b on page 27 says,</b>  18 <b>"additional TVT cases".</b>  19 <b>Are you able to tell me from which case</b>  20 <b>this slide comes?</b>  21 A. I can only tell you that the top  22 panel is from a newer case, and the bottom is  23 likely from an older case.  24 <b>Q. So they're two separate cases?</b>  25 A. Yes.</p>
<p style="text-align: right;">Page 135</p> <p>1 A. That's correct.  2 <b>Q. And it's folded over as a part of</b>  3 <b>the sample preparation process or microtoming</b>  4 <b>process, correct?</b>  5 A. That's correct.  6 <b>Q. This is a 4 micron thick slide,</b>  7 <b>correct?</b>  8 A. About 4 microns, plus or minus.  9 <b>Q. I don't see bark on that</b>  10 <b>polypropylene. Do you see any bark on the</b>  11 <b>polypropylene?</b>  12 A. There is a faint line here, I  13 don't know if it's there or not.  14 <b>Q. When you say "there," you're not</b>  15 <b>pointing to the polypropylene. You're pointing to</b>  16 <b>the circular area to the left of the polypropylene</b>  17 <b>adjacent to the tissue, correct?</b>  18 A. Yeah. Curving linear, yes.  19 <b>Q. And you're suggesting that that</b>  20 <b>may be some bark?</b>  21 A. Yes.  22 <b>Q. And why do you say that?</b>  23 A. Because it looks like it.  24 <b>Q. Okay. And this is magnified at 20</b>  25 <b>times?</b></p>	<p style="text-align: right;">Page 137</p> <p>1 <b>Q. Do you have any idea from looking</b>  2 <b>at this, how long the mesh was implanted in these</b>  3 <b>people?</b>  4 A. No. Not at this magnification.  5 <b>Q. And other than showing the</b>  6 <b>presence of nerves within the mesh scar plate like</b>  7 <b>you did on page 26, is there anything significant</b>  8 <b>about your findings on page 27?</b>  9 A. The only difference is that in top  10 panel, you can clearly see that this nerve is  11 within the pore.  12 <b>Q. Are you suggesting that this nerve</b>  13 <b>is inside of a single pore in the mesh?</b>  14 A. Somewhere within the mesh.  15 <b>Q. Okay. Not within the pore itself?</b>  16 A. It can be within the pore.  17 <b>Q. Do you know?</b>  18 A. It also depends how you define the  19 pore. Pore is a hole in the mesh structure, yes,  20 it is within the space in the mesh structure.  21 <b>Q. This is 20 times magnification,</b>  22 <b>how far is it from one yellow to the other yellow?</b>  23 A. At 1.5 millimeter. Between 1 and  24 1.5 millimeter.  25 <b>Q. Is there anything abnormal about</b></p>

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<p style="text-align: right;">Page 138</p> <p>1 the nerve that's depicted on page 27 in the top</p> <p>2 frame?</p> <p>3 A. It's in the scar and it's in the</p> <p>4 mesh, that is abnormal.</p> <p>5 Q. Other than being in the scar</p> <p>6 plate, is there anything you can tell by light</p> <p>7 microscopy about abnormality in that nerve?</p> <p>8 A. Otherwise, the nerve looks</p> <p>9 healthy, it would conduct pretty healthy pain</p> <p>10 signals.</p> <p>11 Q. Okay. Same thing for the lower</p> <p>12 frame. Other than the presence of the nerve within</p> <p>13 the scar tissue, is there anything that you can</p> <p>14 tell from light microscopy about the general health</p> <p>15 of the nerve?</p> <p>16 A. Same thing, it's not degenerated,</p> <p>17 therefore, it can conduct pain signal.</p> <p>18 Q. As you look at the image on the</p> <p>19 lower left on 3b, the white in that image, again,</p> <p>20 is where polypropylene was?</p> <p>21 A. Yes.</p> <p>22 Q. And as you come down around from</p> <p>23 about 6 o'clock to about 9 o'clock, there's no bark</p> <p>24 there, is there?</p> <p>25 A. No. I don't think so.</p>	<p style="text-align: right;">Page 140</p> <p>1 A. There are two nerves, one is here,</p> <p>2 one is there (indicating).</p> <p>3 Q. And you indicate that with your</p> <p>4 two arrows --</p> <p>5 A. This one is gone.</p> <p>6 Q. Okay.</p> <p>7 A. So it is a location -- it's not</p> <p>8 the nerve itself, it's the location is abnormal.</p> <p>9 Q. Is there anything that you can</p> <p>10 tell me by looking at this image by light</p> <p>11 microscopy that these nerves were producing</p> <p>12 symptoms in the patient?</p> <p>13 A. The question is, if they can.</p> <p>14 Q. Can you tell me by looking at this</p> <p>15 image in set 3c, that these nerves are causing</p> <p>16 symptoms in the patient?</p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: Again, as a pathologist,</p> <p>19 I can only estimate the probability. If it can, if</p> <p>20 it's in abnormal location, if it's causing a lot --</p> <p>21 first of all, it's out of the body now, so it</p> <p>22 cannot cause anything. But when it was in the</p> <p>23 patient, it could.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. Could?</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Let's go to page 28. Page 28 is</p> <p>2 additional TVT cases.</p> <p>3 Is this one mesh or two? One patient</p> <p>4 or two, I guess I should say.</p> <p>5 A. This is hard to say, both are come</p> <p>6 from earlier cases. I probably have thousands of</p> <p>7 images by now, so it will be hard.</p> <p>8 Q. But you can't tell me from which</p> <p>9 patient they come, or which case they're from?</p> <p>10 A. I may or may not be able. It</p> <p>11 would be checking if it's in a specific folder or</p> <p>12 just in pooled images.</p> <p>13 Q. And your description again, below</p> <p>14 is, "Innervation within the mesh scar plate, H&amp;E,</p> <p>15 20 times magnification."</p> <p>16 Other than showing the presence of</p> <p>17 these nerves in the mesh scar plate, is there</p> <p>18 anything that indicates to you by light microscopy</p> <p>19 that these nerves are unhealthy?</p> <p>20 A. Well, it's the location. You see,</p> <p>21 it's slightly curved, it's inside the pore.</p> <p>22 Q. Which one are you talking about</p> <p>23 now, please?</p> <p>24 A. The upper panel.</p> <p>25 Q. Okay, thank you.</p>	<p style="text-align: right;">Page 141</p> <p>1 A. Could produce symptoms all the</p> <p>2 time, or one specific time, or only once in a</p> <p>3 specific moment, it's hard to say.</p> <p>4 Q. And it could be a nerve positioned</p> <p>5 as it is, that never produced any symptoms, true?</p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: Some of them probably not</p> <p>8 producing anything.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. Okay. And the same thing about</p> <p>11 the image below on Figure Set 3c on page 28, other</p> <p>12 than presence of the nerves in the mesh scar plate,</p> <p>13 anything remarkable about this image?</p> <p>14 A. No. Nothing beyond what we've</p> <p>15 discussed.</p> <p>16 Q. Let's go to page 29.</p> <p>17 A. Yes.</p> <p>18 Q. What are we showing on page 29?</p> <p>19 A. The same features of innervation</p> <p>20 of the mesh scar plate. But now in S100 stain.</p> <p>21 Q. Now, is there anything other than</p> <p>22 presence of these nerves in the mesh scar plate</p> <p>23 that indicates to you that these nerves were</p> <p>24 causing pain in the patient?</p> <p>25 A. They are in abnormal location.</p>

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<p style="text-align: right;">Page 142</p> <p>1           <b>Q. And we've already agreed that</b>  2           <b>nerves, even in an abnormal location, may not be</b>  3           <b>producing pain, correct?</b>  4           A. Yes, but more likely they will  5           produce pain.  6           <b>Q. Are you saying that every nerve</b>  7           <b>within the mesh scar plate more likely than not is</b>  8           <b>going to cause pain?</b>  9           A. Through one mechanism or the  10          other, there will be zero mechanism at one point  11          that can produce pain, it may not be chronic pain  12          continuous, but I mean, in a specific movement you  13          have start forming the mesh, so it can cause pain.  14          <b>Q. Let's talk about this for a</b>  15          <b>minute. Doctor, if you look at page 29, and 28,</b>  16          <b>and 27 and 26 --</b>  17          A. Yes?  18          <b>Q. -- it's fair to understand that</b>  19          <b>for every mesh implantation, there are going to be</b>  20          <b>nerves that are going to be in scar tissue.</b>  21          A. Are you talking for all meshes?  22          Regardless of location, or just --  23          <b>Q. I'm talking about slings. Stress</b>  24          <b>urinary incontinence slings, TVT, Prolene.</b>  25          A. So for slings, there will be</p>	<p style="text-align: right;">Page 144</p> <p>1           A. Well, first of all, let's start  2           with 5 percent.  3           That number would have to be specific  4           for our study. There is a range of reported pain  5           anywhere from 5 to 40 plus percent. It depend on  6           methodology, if the patients were followed in time  7           correctly, if there was correctly of follow up  8           time. So the 5 percent is a questionable number.  9           <b>Q. Can I interrupt you there, if you</b>  10          <b>don't mind. Let's take your upper bound of</b>  11          <b>40 percent?</b>  12          A. Yes.  13          <b>Q. So you have, by your own</b>  14          <b>statement, even in the worse case scenario, you</b>  15          <b>have 60 percent of the sling patients who don't</b>  16          <b>experience pain, correct?</b>  17          A. Who do not complain to the point  18          when it's recorded.  19          There are multiple reasons why it may  20          not be recorded, they may still experience some  21          pain. Maybe it's not serious enough to be  22          recorded, maybe it's not serious enough -- there  23          will be some patients which have no pain at all.  24          There will be some patients which have so little  25          pain, only in a specific moment, that it's not</p>
<p style="text-align: right;">Page 143</p> <p>1           innervation, at least those samples I examined,  2           there will be innervation in all of them.  3           <b>Q. Okay. And complaints of pain for</b>  4           <b>slings, TVT slings, you'll agree is less than 5</b>  5           <b>percent?</b>  6           MR. ORENT: Objection.  7           THE WITNESS: For the specimens I  8           received?  9           BY MR. THOMAS:  10          <b>Q. I'm talking about the studies on</b>  11          <b>the topic?</b>  12          MR. ORENT: Objection. Outside the  13          scope.  14          THE WITNESS: Now we're talking about  15          what I received and what is still in the patients.  16          Because studies were clinically done based on  17          clinical -- clinical symptoms for the samples or  18          slings which are still in the body.  19          BY MR. THOMAS:  20          <b>Q. Very simple question.</b>  21          <b>How do you explain findings in the</b>  22          <b>clinical studies that pain is a complaint of</b>  23          <b>patients in less than 5 percent of the time, when</b>  24          <b>you say in every mesh that you see, that there are</b>  25          <b>nerves within the scar plate?</b></p>	<p style="text-align: right;">Page 145</p> <p>1           worth reporting. Some of them don't report it and  2           so forth.  3           And then there will be patients that  4           there is so severe pain, the mesh needs to come  5           out. There will be a range of sensations and  6           personal perception.  7           So, from my perspective, when I examine  8           specimens, I report what is abnormal. To what  9           degree it's causing clinical symptoms, it depends  10          on many factors. If you want to -- you cannot look  11          at the human body as a machine. I mean, there is  12          part missing, it's not going to work. Or if there  13          is wire loose, I mean, it may cause some problems.  14          So, there will be a range of -- or  15          degree of pain sensation and a range of personal  16          attitude so this will effect the recording of  17          clinical symptoms.  18          On the histology side, again, there  19          will be a range of how many nerves are involved,  20          one or two, or a really high density. To what  21          degree they are involved, some of them will have  22          such a strong deformation, that there is  23          100 percent probability that it will cause pain.  24          <b>Q. Let me ask this question --</b>  25          A. So that's the complexity of the</p>

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<p style="text-align: right;">Page 146</p> <p>1 situation. I mean you cannot separate it sharply,  2 okay, 5 percent for this, 5 percent for that. It  3 can cause a pain. This is abnormal location, this  4 is abnormal situation, this is a pathological  5 finding.  6 <b>Q. Let's talk about this for a</b>  7 <b>minute. So the pages we've just been through,</b>  8 <b>we've talked about, on pages 26, 27, 28 and 29, and</b>  9 <b>it goes on to 30 and 31, and on to 33. But just</b>  10 <b>for those for now.</b>  11 <b>Is it fair to understand that in every</b>  12 <b>mesh that you've analyzed - regardless of</b>  13 <b>manufacturer - in the pelvic floor, for treatment</b>  14 <b>of stress urinary incontinence, you find nerves in</b>  15 <b>scar tissue?</b>  16 A. Yes.  17 <b>Q. Okay.</b>  18 A. The degree of innervation will be  19 different, there will be a degree of also nerve  20 deformation within the mesh, but strictly saying  21 there will be innervation of the scar plate in  22 almost all patients.  23 <b>Q. Have you made any attempt to</b>  24 <b>differentiate across manufacturers, the extent to</b>  25 <b>which the innervation of the scar plate varies?</b></p>	<p style="text-align: right;">Page 148</p> <p>1 -- REPORTER'S NOTE: Question read as  2 recorded above.  3 THE WITNESS: Oh, as I said, I can only  4 testify or make opinions of what came out of the  5 specimen. And I told you earlier, that there is --  6 I have been dealing with those specimens which  7 caused complications already.  8 BY MR. THOMAS:  9 <b>Q. For every mesh sample that you've</b>  10 <b>looked at for mesh use for the treatment of stress</b>  11 <b>urinary incontinence, have you found mesh</b>  12 <b>innervation in the scar tissue?</b>  13 A. Almost all, yes.  14 <b>Q. Any you haven't?</b>  15 A. If it was a small sample, maybe  16 one or two, I couldn't find nerves.  17 <b>Q. Is that because -- do you have an</b>  18 <b>opinion, is that because the sample was too small,</b>  19 <b>because it didn't exist, or do you have an opinion?</b>  20 A. I cannot say beyond that, I just  21 didn't find it. It could be sampling issue, it  22 could be not. Again, I cannot state what I don't  23 know.  24 <b>Q. And how many have you seen?</b>  25 A. Individual cases.</p>
<p style="text-align: right;">Page 147</p> <p>1 A. No.  2 <b>Q. Have you made any attempt to</b>  3 <b>differentiate across types of mesh products, the</b>  4 <b>extent to which nerve innervation varies?</b>  5 A. I may in the future, I haven't  6 done it yet. But I may in the future.  7 <b>Q. Okay. So is it fair for me to</b>  8 <b>understand, and the record to reflect, that for</b>  9 <b>every mesh implanted for the treatment of stress</b>  10 <b>urinary incontinence, it's your opinion that there</b>  11 <b>will be nerve innervation within scar plate, that</b>  12 <b>you think is capable of causing pain?</b>  13 MR. ORENT: Objection. I think his  14 testimony is every mesh that he's looked at.  15 Manufactured, that he's looked at.  16 I don't think Dr. Iakovlev has any  17 opinions about mesh he's never looked at, brands  18 he's never looked.  19 THE WITNESS: Yeah, that's correct.  20 BY MR. THOMAS:  21 <b>Q. Okay. Let me ask you this question --</b>  22 A. Let's repeat the question, then I  23 can answer it in more...  24 MR. THOMAS: Would you read it back,  25 please?</p>	<p style="text-align: right;">Page 149</p> <p>1 <b>Q. How many have you seen?</b>  2 A. Less than five.  3 <b>Q. How many total cases have you</b>  4 <b>seen?</b>  5 A. Oh, from slings?  6 <b>Q. Yes.</b>  7 A. About 100.  8 <b>Q. About 100. And less than five you</b>  9 <b>have not seen nerve innervation within scar tissue?</b>  10 A. Yes.  11 <b>Q. And you don't know whether that's</b>  12 <b>because it is a sampling error or because there</b>  13 <b>wasn't any nerves in the scar plate?</b>  14 A. That's correct.  15 <b>Q. Is it fair to say, based on your</b>  16 <b>experience as a pathologist, that you would expect</b>  17 <b>that when mesh is placed for the treatment of</b>  18 <b>stress urinary incontinence, that nerves would be</b>  19 <b>encapsulated by the scar tissue in the healing</b>  20 <b>process?</b>  21 A. They can. If they become trapped  22 in the scar tissue, each single implanted mesh, we  23 would have to do autopsy series. I cannot go  24 beyond what I see in explanted meshes, and all  25 explanted meshes came out for complications. And</p>

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<p style="text-align: right;">Page 150</p> <p>1 almost all of them, or a large proportion had pain 2 as a symptom. 3 <b>Q. Again, the cases you've received</b> 4 <b>have been complications?</b> 5 A. Yes. 6 <b>Q. And of course you know that people</b> 7 <b>have mesh removed for reasons other than pain,</b> 8 <b>don't you?</b> 9 A. In hernia surgery, yes. 10 <b>Q. Do you know whether or not</b> 11 <b>patients have mesh removed for reasons other than</b> 12 <b>pain?</b> 13 MR. ORENT: Objection. 14 THE WITNESS: There might be an 15 overwhelming other complaint, like erosion or 16 infection, but in almost -- I don't want to stick a 17 number, but most of these patients complain of some 18 degree of pain. 19 BY MR. THOMAS: 20 <b>Q. Have you have investigated, as a</b> 21 <b>part of your work in this case, the reasons why</b> 22 <b>patients have mesh removed?</b> 23 A. There's always a reason. 24 <b>Q. I understand that. Do you know</b> 25 <b>what they are, and percentage wise, how they</b></p>	<p style="text-align: right;">Page 152</p> <p>1 THE WITNESS: No, it's combined. It 2 can be combined, this pain. 3 BY MR. THOMAS: 4 <b>Q. Okay.</b> 5 A. To cause void and dysfunction, 6 even to compress urethra to a degree that the 7 outflow is obstructed. 8 <b>Q. Are you aware of any studies which</b> 9 <b>have analyzed meshes removed because of pain,</b> 10 <b>compared to meshes removed for other reasons in</b> 11 <b>comparing the histology of those meshes?</b> 12 A. We're doing some work in hernia 13 specimens. 14 <b>Q. But in terms of published</b> 15 <b>peer-reviewed studies today, are you aware of any</b> 16 <b>studies out there, which compare the histology of</b> 17 <b>meshes removed for pain, and meshes removed for</b> 18 <b>non-pain reasons?</b> 19 A. That's a very good question. Why, 20 after 50 years and a large proportion of specimens 21 removed for pain, there is no histology study. Why 22 has this not been done? 23 <b>Q. So did you do a literature search</b> 24 <b>of that?</b> 25 A. Of course I did.</p>
<p style="text-align: right;">Page 151</p> <p>1 <b>breakout across a patient population?</b> 2 A. You mean the driving reasons for 3 implantation? 4 <b>Q. Yes.</b> 5 A. It's in the paper. At least in 6 those 164 samples. 7 <b>Q. And that's the paper you did with</b> 8 <b>Dr. Blaivas?</b> 9 A. No. The degradation paper. 10 <b>Q. Okay.</b> 11 A. But there's always a driving 12 reason for explantation. There may be driving 13 reason for explantation is erosion, but then pain 14 is attributed to erosion. So it's not indicated as 15 a main reason of explantation. 16 <b>Q. You can have voiding dysfunction?</b> 17 A. Okay. In a voiding dysfunction, 18 but again, voiding dysfunction usually what 19 happens, you have a strong compression against 20 urethra, and this produces pain due to compression. 21 So there will be a mixture of mechanisms for pain. 22 <b>Q. Are you suggesting that voiding</b> 23 <b>dysfunction is subsumed within the pain that's</b> 24 <b>reported in these studies?</b> 25 MR. ORENT: Objection.</p>	<p style="text-align: right;">Page 153</p> <p>1 <b>Q. And you didn't find any studies</b> 2 <b>that compared the histology of mesh removed from</b> 3 <b>patients who complained of pain, compared to the</b> 4 <b>histology of patients who had mesh removed for</b> 5 <b>non-pain reasons?</b> 6 A. There were descriptions in hernia 7 publications. I mean in meshes removed for hernia 8 repair. 9 <b>Q. Which studies, do you remember?</b> 10 A. 2005, Klosterhalfen. He put the 11 picture of deformed nerve, and he states that in 12 his experience, over 60 percent of the meshes 13 removed for pain have some degree of nerve 14 involvement. 15 <b>Q. Do you view Dr. Klosterhalfen as</b> 16 <b>authoritative in this area?</b> 17 A. Yes. He's an authority, he's one 18 of the oldest researchers. 19 <b>Q. Do you know whether Dr.</b> 20 <b>Klosterhalfen has ever investigated the precise</b> 21 <b>question about whether the histology of mesh</b> 22 <b>removed for indications of pain is different from</b> 23 <b>the histology of mesh for -- from patients removed</b> 24 <b>for non-pain reasons?</b> 25 A. That's what he stated. Over</p>

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<p style="text-align: right;">Page 154</p> <p>1 60 percent of the specimens removed for pain showed 2 nerve involvement.</p> <p>3 MR. ORENT: Before we go on to the next 4 question, you had cut Dr. Iakovlev off from 5 answering. He started to say "but there are other 6 authors", if you want to just continue.</p> <p>7 THE WITNESS: Yes. There are other 8 descriptors of meshes removed for pain, and they 9 would find nerve involvement with traumatic 10 neuroma. Those are, I think individual cases, not 11 the series.</p> <p>12 Again, same histology. They were 13 trying to figure out what was wrong, what was 14 causing pain, and they found nerve involvement. 15 And that was done before I started researching my 16 nerves.</p> <p>17 BY MR. THOMAS: 18 <b>Q. Would you expect more or less</b> 19 <b>inflammation to be seen in histology of meshes</b> 20 <b>removed for pain than meshes removed for non-pain</b> 21 <b>reasons?</b></p> <p>22 A. To a degree. My research in 23 hernia showed that foreign body inflammation is a 24 component of pain mechanism. So those meshes which 25 were removed for pain only, they continue to have</p>	<p style="text-align: right;">Page 156</p> <p>1 there's a pool, if we collect enough, we can see 2 the difference. For each individual patient, how 3 much of this feature, or that feature is playing a 4 role in each individual symptom, will be very 5 different from patient to patient.</p> <p>6 So overall, the higher degree of 7 foreign body reaction is associated with higher 8 rates for chronic pain.</p> <p>9 <b>Q. And that's based on your research</b> 10 <b>or other published research?</b></p> <p>11 A. Foreign body has been worked up 12 quite a bit in published histological studies. How 13 much of that was specifically determined, comparing 14 two groups or three groups, it's difficult to say, 15 I don't remember right now.</p> <p>16 So it is a combination of what was 17 published before, and what I find in my samples, so 18 that's -- that would be a basis for my opinion.</p> <p>19 <b>Q. Is it your opinion that results in</b> 20 <b>the hernia literature on the issue of association</b> 21 <b>between inflammation and pain, are transferrable to</b> 22 <b>the pelvic floor?</b></p> <p>23 A. Some are, yes. Not everything, 24 but some are.</p> <p>25 <b>Q. Okay. And why would it not be?</b></p>
<p style="text-align: right;">Page 155</p> <p>1 relatively steady, pronounced foreign body reaction 2 many years after implantation.</p> <p>3 And those which were removed for 4 recurrence, they show a trend down. So at the 5 beginning, there is inflammation, then it goes 6 down.</p> <p>7 So by the time of explantation, if it 8 happens eight years or ten years after 9 explantation, foreign bodies subsided; which is 10 different from those which were removed for pain.</p> <p>11 <b>Q. So are you able, from your</b> 12 <b>research, in your work, to form an opinion as to</b> 13 <b>whether mesh removed for purposes of pain, the</b> 14 <b>histology will show higher rates of inflammation</b> 15 <b>than the histology for meshes removed for non-pain</b> 16 <b>reasons?</b></p> <p>17 A. So before we go into the 18 individual findings, you're trying to split it into 19 what is causing the pain, nerve entrapment and 20 inflammation or something else.</p> <p>21 This is a complex process. There are 22 multiple factors which are playing, together with 23 patient perception of pain and reporting of pain.</p> <p>24 So with this type of complexity, we 25 cannot separate one individual feature. Overall,</p>	<p style="text-align: right;">Page 157</p> <p>1 A. There are different anatomical 2 locations, different physical factors acting on the 3 scar plate. It also crosses many anatomical planes 4 in the pelvis. While in the abdominal wall, and 5 it's parallel to anatomical planes.</p> <p>6 <b>Q. I'm trying to get through this for</b> 7 <b>a second. If you'll look at pages 30, 31, 32 and</b> 8 <b>33. Are the images on those pages additional</b> 9 <b>depictions of nerves within the mesh scar plate?</b></p> <p>10 A. That's correct.</p> <p>11 <b>Q. Is there anything else significant</b> 12 <b>about those images other than they show innervation</b> 13 <b>within the mesh scar plate?</b></p> <p>14 A. No.</p> <p>15 <b>Q. On page 33, Figure Set 3h, in the</b> 16 <b>upper right-hand corner, you've called out what</b> 17 <b>you've described as a "neurovascular bundle"; what</b> 18 <b>is that?</b></p> <p>19 A. Most of the larger nerves in the 20 medium size arteries, become together. One artery, 21 two veins, and one nerve, that's how it works. And 22 the nerve just starts bleeding, so the nerve goes 23 its way and artery goes its own way.</p> <p>24 So in this specific case, an artery and 25 a nerve are still together.</p>

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<p style="text-align: right;">Page 158</p> <p>1 <b>Q. Okay. The brown is the nerve,</b>  2 <b>correct?</b>  3 A. Yes. I mean, there are some other  4 brown, probably picking up some other stuff, but  5 this is --  6 <b>Q. Where is the artery?</b>  7 A. In the blue. You can see  8 streaming, it's not a really high resolution.  9 <b>Q. What is the significance of the</b>  10 <b>neurovascular bundle as depicted in that image?</b>  11 A. Well, see, it is in the tight  12 spot. So this is really as compartmentalized as it  13 gets, and slightly deformed.  14 So if you move this mesh around, the  15 fibers will start compressing on the neurovascular  16 bundle. It may cause obliteration of the artery,  17 or can impinge the nerve.  18 <b>Q. Is there any impingement shown in</b>  19 <b>this image?</b>  20 A. Well, it's deformed.  21 <b>Q. Is there any impingement shown?</b>  22 A. It does, because it's deformed,  23 it's curved.  24 <b>Q. And you're referring now to the</b>  25 <b>lower right-hand image?</b></p>	<p style="text-align: right;">Page 160</p> <p>1 <b>Q. Do you know?</b>  2 MR. ORENT: Objection.  3 THE WITNESS: With 100 percent  4 certainty, no.  5 BY MR. THOMAS:  6 <b>Q. Okay. And you talked about an</b>  7 <b>obliteration of the artery. Does the image on</b>  8 <b>page 33 in the upper right show an obliteration of</b>  9 <b>the artery?</b>  10 A. No, not this image.  11 <b>Q. Other than the nerve impingement</b>  12 <b>that you've described, and the potential for</b>  13 <b>obliteration of the artery, is there anything</b>  14 <b>unusual about the depiction of the nerves in those</b>  15 <b>images?</b>  16 A. No.  17 <b>Q. And I need you to go back, because</b>  18 <b>I didn't ask you that question about the prior two</b>  19 <b>pages, 30 through 32.</b>  20 <b>Other than the depiction of the nerves</b>  21 <b>within the scar plate, is there anything about the</b>  22 <b>nerves that are seen there that cause you any</b>  23 <b>concern about the potential of those nerves to</b>  24 <b>cause injury?</b>  25 MR. ORENT: Objection.</p>
<p style="text-align: right;">Page 159</p> <p>1 A. That's correct.  2 <b>Q. Is there anything you can tell by</b>  3 <b>looking at that image, whether that curved nerve</b>  4 <b>was causing pain in this patient?</b>  5 A. I can say the probability of this  6 causing pain is much higher than a nerve which is  7 not deformed. Like something like this on page 31.  8 <b>Q. You can't rule out by looking at</b>  9 <b>the image on page 33, where you show the curved</b>  10 <b>nerve, you can't rule out that that nerve is not</b>  11 <b>causing pain, correct?</b>  12 A. I think we're going back to the  13 same issue. You're taking human body as a machine,  14 it's not. Medicine doesn't happen like that. So  15 there are many, many, many factors which cause.  16 If the same image we put in MRI image,  17 and this deformation would be on the root coming  18 from the back, the radiologist would report that  19 there's impingement of a root. And that's how back  20 pain occurs that's radiating to the leg, and so  21 forth. So this is a much smaller scale, the same  22 mechanism.  23 <b>Q. Do you know whether this patient</b>  24 <b>was complaining of pain?</b>  25 A. Most likely she was.</p>	<p style="text-align: right;">Page 161</p> <p>1 THE WITNESS: So going back to  2 mechanisms of pain. So there are two mechanisms,  3 or two major groups of mechanisms to cause pain.  4 First, you affect the nerve itself. So you impinge  5 it, squeeze it, becomes deformed and that can be  6 felt as pain, the nerve itself, the nerve trunk.  7 The second group of mechanisms is when  8 you affect the receptors. And the receptors can be  9 affected, it can be again a mechanical trauma,  10 cutting, compressing, burning, chemical trauma,  11 ischemia, then the receptors are signalling pain  12 through the nerve. So for smaller branches, the  13 significance is that the receptors now can pick up  14 the signal of nerves -- of pain, and then it will  15 be delivered through these branches, so it just  16 shows that this tissue can sense pain.  17 BY MR. THOMAS:  18 <b>Q. Okay. This tissue is capable of</b>  19 <b>sensing pain?</b>  20 A. Yes.  21 <b>Q. Not that it is in fact sensing</b>  22 <b>pain in the body at the time?</b>  23 A. If you have other mechanisms to  24 deliver pain, it will be -- it will be causing  25 pain.</p>

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<p>1 <b>Q. Correct.</b></p> <p>2 A. Now, if you go to page 33, this</p> <p>3 will be an example where it would be directly</p> <p>4 effecting the nerve trunk. Impingement of the</p> <p>5 nerve.</p> <p>6 <b>Q. Now, are you able, in these</b></p> <p>7 <b>images, 30 to 33, to show me any nerve receptors?</b></p> <p>8 A. You mean receptors, nerve endings.</p> <p>9 When it goes really small, you can see really</p> <p>10 fiber, and it is -- most of the ends will have no</p> <p>11 staining, because they just disappear. But I mean,</p> <p>12 you'd have to go in higher magnification.</p> <p>13 <b>Q. So with the magnification you have</b></p> <p>14 <b>here, you're not able to identify any nerve</b></p> <p>15 <b>receptors; is that fair?</b></p> <p>16 A. No, not in these pictures. It's</p> <p>17 too small magnification.</p> <p>18 <b>Q. I have to ask the question again</b></p> <p>19 <b>because you answered "no" to a negative question.</b></p> <p>20 <b>It's fair to understand that based on</b></p> <p>21 <b>the magnification that you have in these images on</b></p> <p>22 <b>pages 30 to 33, you can't identify any nerve</b></p> <p>23 <b>receptors, correct?</b></p> <p>24 A. I cannot see nerve receptors at</p> <p>25 this degree of magnification.</p>	<p>1 <b>and the lower one was four times; is that correct?</b></p> <p>2 A. It's a typo, it should be 40.</p> <p>3 <b>Q. 40?</b></p> <p>4 A. 40. Somewhere between 40 X and 50 X.</p> <p>5 Again, the cropping factor there, the magnification</p> <p>6 there is not exactly...</p> <p>7 <b>Q. And these are, again, additional</b></p> <p>8 <b>TVT cases, and you have not supplied us the slides</b></p> <p>9 <b>for these cases, correct?</b></p> <p>10 MR. ORENT: Objection.</p> <p>11 BY MR. THOMAS:</p> <p>12 <b>Q. In this case?</b></p> <p>13 A. That's correct. These are</p> <p>14 previous TVT cases.</p> <p>15 <b>Q. On page 35 --</b></p> <p>16 A. Yes.</p> <p>17 <b>Q. -- you suggest degeneration of</b></p> <p>18 <b>affected nerves; tell me what you mean by that?</b></p> <p>19 A. So you see the inner portion of</p> <p>20 the nerve lost myelination. So there is</p> <p>21 degeneration of myelin sheath in the nerves. It</p> <p>22 means that these nerves cannot deliver, or most</p> <p>23 likely not deliver irregular signals.</p> <p>24 So earlier you were asking about the</p> <p>25 abnormality, this is the abnormality that we're</p>
Page 163	Page 165
<p>1 <b>Q. Thank you.</b></p> <p>2 <b>If you go to page 34, what is the</b></p> <p>3 <b>significance of this image?</b></p> <p>4 A. This shows another severely</p> <p>5 deformed nerve. So this would be a mechanism for</p> <p>6 pain through impingement.</p> <p>7 <b>Q. And the severely deformed nerve as</b></p> <p>8 <b>you described it, is the brown portion, stained</b></p> <p>9 <b>brown?</b></p> <p>10 A. The dark brown portion or dark</p> <p>11 brown structure.</p> <p>12 <b>Q. And in the lower left-hand corner,</b></p> <p>13 <b>the white area is where the polypropylene is or</b></p> <p>14 <b>was, correct?</b></p> <p>15 A. That's correct.</p> <p>16 <b>Q. And what's the significance of the</b></p> <p>17 <b>dark blue and the border of that area? Is that the</b></p> <p>18 <b>staining mechanism, or does that tell you anything?</b></p> <p>19 A. Can you point it? So significance</p> <p>20 of what?</p> <p>21 <b>Q. The darker blue.</b></p> <p>22 A. This dark blue?</p> <p>23 <b>Q. Yes.</b></p> <p>24 A. That's inflammation.</p> <p>25 <b>Q. Okay. And the upper is 2.5 power,</b></p>	<p>1 talking about, this is the nerve degeneration. In</p> <p>2 this case, if this part is sensory, inside, it</p> <p>3 means that the area is numb.</p> <p>4 This part of the nerve cannot sense</p> <p>5 pain or innervation of that part of the body, which</p> <p>6 goes through this nerve, may not experience any</p> <p>7 pain; it's numb.</p> <p>8 <b>Q. And that's the portion you're</b></p> <p>9 <b>referring to in the lower right-hand image with the</b></p> <p>10 <b>arrow, correct?</b></p> <p>11 A. That's correct. So the</p> <p>12 abnormality of the neural section indicates the</p> <p>13 other process, of loss of sensation, loss of pain</p> <p>14 sensation.</p> <p>15 <b>Q. Do you know what a Renault body is?</b></p> <p>16 A. Say that again.</p> <p>17 <b>Q. Do you know what a Renault body is?</b></p> <p>18 <b>R-E-N-A-U-T.</b></p> <p>19 A. I think I've seen this term, but I</p> <p>20 don't remember it.</p> <p>21 <b>Q. Okay. Does the S100 stain all</b></p> <p>22 <b>components of the nerve?</b></p> <p>23 A. It only stains schwann cells.</p> <p>24 <b>Q. When you reached the opinion on</b></p> <p>25 <b>page 35 that that shows a degeneration of the</b></p>

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<p style="text-align: right;">Page 166</p> <p>1 <b>nerve, did you rule out the presence of nerve</b>  2 <b>structures other than schwann cells that might be</b>  3 <b>present?</b>  4 A. There might be axons still there,  5 but that's not the point. The point is the nerve  6 is degenerating.  7 <b>Q. And what's the clinical impact of</b>  8 <b>the degenerated nerve?</b>  9 A. I just told you. There are  10 fibers, which are in the area, mainly not function.  11 It means that if they are sensory fibers, they may  12 not deliver signals. So that area which is  13 innervated through those fibers, will be numb. You  14 will not feel anything in that area.  15 <b>Q. So it will not cause pain?</b>  16 A. In the reverse, it will not feel  17 anything.  18 <b>Q. But if it doesn't feel anything,</b>  19 <b>does that mean that it does not cause pain?</b>  20 A. Including pain. It will not feel  21 touch, it will not feel temperature, it will not  22 feel pain.  23 <b>Q. Okay. Anything else remarkable</b>  24 <b>about it then?</b>  25 A. No.</p>	<p style="text-align: right;">Page 168</p> <p>1 <b>on page 36 -- strike that.</b>  2 <b>This is one image, the second one</b>  3 <b>you've labeled, so it's just one image?</b>  4 A. That is correct.  5 <b>Q. Is there anything about the image</b>  6 <b>on page 36, that you can tell by light microscopy,</b>  7 <b>that there's anything abnormal about the ganglia</b>  8 <b>that's depicted there?</b>  9 A. To begin with, as we saw the  10 nerves, the location was abnormal. So it's in the  11 scar tissue and it's inside the mesh.  12 <b>Q. Is that the only thing about this</b>  13 <b>image and the ganglia that causes you concern?</b>  14 A. No.  15 <b>Q. What else?</b>  16 A. I mean, that's about it. I don't  17 have any other concerns.  18 <b>Q. Thank you. Page 37 you have:</b>  19 <b>"Innervation of mucosa overlying the mesh, H&amp;E and</b>  20 <b>S100 of the same tissue area, four times.</b>  21 <b>Additional TVT cases."</b>  22 <b>Again, these are cases outside of the</b>  23 <b>consolidated group, correct?</b>  24 A. That is correct.  25 <b>Q. And are all these images just four</b></p>
<p style="text-align: right;">Page 167</p> <p>1 <b>Q. If you go to page 36, Figure Set 4.</b>  2 A. Yes.  3 <b>Q. You have, "A neural ganglia in</b>  4 <b>additional TVT cases."</b>  5 <b>Again, these are cases that you</b>  6 <b>previously worked up?</b>  7 A. That is correct.  8 <b>Q. What is a neural ganglia?</b>  9 A. Neural ganglion is like a switch  10 box, or connection box for the autonomous  11 neuro system. The neuro system which is  12 innervating in the organs rather than skin and  13 mucosa.  14 <b>Q. What is the significance of the</b>  15 <b>presence of this image of the neural ganglion?</b>  16 A. It tells you that some of the  17 nerves, which we see in the specimens are  18 autonomous. So some of them go into the bladder.  19 That's one -- well, one important aspect of this.  20 The second important aspect is that the  21 ganglia themselves can be affected by the image.  22 So in first case, the nerves can be  23 affected, which are further away from the ganglia.  24 And second case scenario, the ganglia themselves.  25 <b>Q. Is there anything about this image</b></p>	<p style="text-align: right;">Page 169</p> <p>1 <b>times?</b>  2 A. The degree of magnification on the  3 top image is slightly lower, and magnification on  4 the lower is slightly higher. Again, this is  5 not -- it's hard to say exactly what's the degree  6 of magnification. Because they've been taken  7 through a camera and sort of objective, and then  8 cropped, and then resized to be reprinted so...  9 <b>Q. What is the significance of the</b>  10 <b>image on the top where you showed mucosa, distorted</b>  11 <b>mucosa, and a measurement of 1 millimeter?</b>  12 A. Significance is that the mesh is  13 right under the mucosa. So, if you touch the  14 mucosa, even if it's light pressure, it immediately  15 gets compressed into the mesh. It can be exposed,  16 I mean, the mucosa can breakdown.  17 <b>Q. This is from the Edwards case,</b>  18 <b>isn't it?</b>  19 A. It could be, I don't know. It's  20 old picture, it could be from the Edwards case.  21 <b>Q. And this does not show an</b>  22 <b>exposure, correct?</b>  23 A. It's not exposed, yes.  24 <b>Q. It's not an erosion either yet?</b>  25 A. In this specific image, it's not</p>

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<p style="text-align: right;">Page 170</p> <p>1 exposed.</p> <p>2 <b>Q. Okay. And what's the significance</b></p> <p>3 <b>of the distorted mucosa?</b></p> <p>4 A. Probably, it was getting close to</p> <p>5 the exposure site. I don't remember specifics.</p> <p>6 <b>Q. Okay. But is it simply the fact</b></p> <p>7 <b>of the location of this mesh related to the mucosa</b></p> <p>8 <b>that you're pointing out here?</b></p> <p>9 A. That is correct.</p> <p>10 <b>Q. Is that a surgical placement issue?</b></p> <p>11 A. Not exactly. It can migrate, it</p> <p>12 can move centimeters within the body.</p> <p>13 <b>Q. Or a surgeon can place it there,</b></p> <p>14 <b>correct?</b></p> <p>15 A. Both.</p> <p>16 <b>Q. Yes. And you're not able to tell</b></p> <p>17 <b>from this image, whether the surgeon placed it</b></p> <p>18 <b>there or it moved there from somewhere else,</b></p> <p>19 <b>correct?</b></p> <p>20 A. No. I know that all of them are</p> <p>21 covered by mucosa after surgery. That's what</p> <p>22 surgeons are trying to do.</p> <p>23 <b>Q. So again, I asked a bad question.</b></p> <p>24 <b>You can't tell from looking at the</b></p> <p>25 <b>image, whether the surgeon placed it there, or</b></p>	<p style="text-align: right;">Page 172</p> <p>1 <b>anything else remarkable about that image?</b></p> <p>2 A. No.</p> <p>3 <b>Q. If we go to page 39, what is</b></p> <p>4 <b>vascular dilatation?</b></p> <p>5 A. When the vessels are being</p> <p>6 distended, so the outflow from the vessels is</p> <p>7 obstructed for varying reasons. So there is more</p> <p>8 fluid coming in, than fluid coming out.</p> <p>9 <b>Q. And what does mesh have to do with</b></p> <p>10 <b>vascular dilatation?</b></p> <p>11 A. It caused it.</p> <p>12 <b>Q. How do you know that?</b></p> <p>13 A. Because normally vessels are not</p> <p>14 distended like this, there is a reason why the</p> <p>15 outflow is obstructed.</p> <p>16 <b>Q. Are there any other causes for</b></p> <p>17 <b>vascular dilatation?</b></p> <p>18 A. In normal tissue?</p> <p>19 <b>Q. Yes.</b></p> <p>20 A. There are some other, like typical</p> <p>21 example is hemorrhoids.</p> <p>22 <b>Q. I'm sorry?</b></p> <p>23 A. Hemorrhoids.</p> <p>24 <b>Q. Hemorrhoids?</b></p> <p>25 A. Hemorrhoids.</p>
<p style="text-align: right;">Page 171</p> <p>1 <b>whether it migrated there, correct?</b></p> <p>2 A. That's correct.</p> <p>3 <b>Q. Thank you. And what's the</b></p> <p>4 <b>significance of the two images below that on</b></p> <p>5 <b>Figure Set 5?</b></p> <p>6 A. It's the same image, the right</p> <p>7 copy is labeled, the left one is not labeled. It</p> <p>8 shows that the tissue in between mucosa and the</p> <p>9 mesh is innervated.</p> <p>10 <b>Q. I see.</b></p> <p>11 A. So if you compress mucosa, you are</p> <p>12 hitting the receptors, hence small nerve branches</p> <p>13 at the same time.</p> <p>14 <b>Q. Anything abnormal about the nerve</b></p> <p>15 <b>branches and twigs that you depict in those images?</b></p> <p>16 A. Just the location.</p> <p>17 <b>Q. Okay. Page 38, "Additional TVT</b></p> <p>18 <b>cases." What does this show?</b></p> <p>19 A. The same as it says on the</p> <p>20 previous page, superficial location of the mesh,</p> <p>21 overlying mucosa, innervation of the tissue and the</p> <p>22 mucosa.</p> <p>23 <b>Q. And other than the presence of the</b></p> <p>24 <b>nerves in the mucosa, and the position of those</b></p> <p>25 <b>nerves relative to the mesh in the mucosa, is there</b></p>	<p style="text-align: right;">Page 173</p> <p>1 <b>Q. I'm sorry. That's a southern West</b></p> <p>2 <b>Virginia way of saying it, I apologize.</b></p> <p>3 A. Okay. So there is dilatation of</p> <p>4 the vascular structure, blood stays in. If it's</p> <p>5 lymphatic vessel, lymph will stay, so it will</p> <p>6 distend and it becomes larger.</p> <p>7 <b>Q. Now, what is stasis, S-T-A-T-I-S?</b></p> <p>8 A. Stasis, sorry.</p> <p>9 <b>Q. Stasis. So stasis and tissue</b></p> <p>10 <b>edema; what does that mean?</b></p> <p>11 A. Stasis means that the fluid is</p> <p>12 stagnant in the vessels. So it accumulates there,</p> <p>13 it doesn't outflow. And then after some time, this</p> <p>14 fluid starts seeping into the tissue. So because</p> <p>15 the blood vessels, or lymphatics are so backed up,</p> <p>16 fluid starts going into the tissue; that's how</p> <p>17 edema happens.</p> <p>18 <b>Q. Okay. The blue in the image is</b></p> <p>19 <b>polypropylene?</b></p> <p>20 A. Yes.</p> <p>21 <b>Q. And that is moved in the image by</b></p> <p>22 <b>sample preparation?</b></p> <p>23 A. That's correct.</p> <p>24 <b>Q. The artifacts?</b></p> <p>25 A. Yes.</p>

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<p>1 <b>Q. And do you see any bark around the</b>  2 <b>polypropylene in those images?</b>  3 A. Here.  4 <b>Q. You pointed to the white. I'm</b>  5 <b>looking at the blue polypropylene itself. There's</b>  6 <b>no bark attached to any of the polypropylene, is</b>  7 <b>there?</b>  8 A. Probably there is, but so low  9 magnification. I can see it clearly in this space.  10 <b>Q. And you're referring now to the</b>  11 <b>upper right-hand corner and the black mark at the</b>  12 <b>lower right, correct?</b>  13 A. Just above it -- no, no, here.  14 <b>Q. Are you talking about --</b>  15 A. The faint line. This faint line.  16 (Indicating).  17 <b>Q. Oh, I see, okay.</b>  18 <b>And what's the clinical significance of</b>  19 <b>the vascular dilatation and stasis tissue edema?</b>  20 A. There's pressure inside. If fluid  21 accumulates to a degree, and then it starts  22 pressing in tissue, there will be pressure  23 accumulating.  24 <b>Q. And to what extent can you</b>  25 <b>determine whether this pressure is present in an</b></p>	<p>1 Take hemorrhoids, you ask some patients, have them  2 painful; some patients have them not painful.  3 BY MR. THOMAS:  4 <b>Q. I understand that. But it's also</b>  5 <b>fair to understand that this woman may have had</b>  6 <b>this issue in the histology, as you've described</b>  7 <b>it, but not be experiencing any symptoms because of</b>  8 <b>it, correct?</b>  9 A. That's correct. The main thing is  10 it's an abnormal finding and it can cause pain.  11 <b>Q. Okay. Do you know whether the</b>  12 <b>images that are on page 40 are --</b>  13 A. Stasis.  14 <b>Q. It's the same patient, 6a, 6b?</b>  15 A. Could be, I'm not sure.  16 <b>Q. You don't know, okay.</b>  17 <b>Again, the blue is polypropylene?</b>  18 A. Yes.  19 <b>Q. Are you able to tell in 6b, the</b>  20 <b>long, narrow white space in the lower left hand,</b>  21 <b>whether that is polypropylene that's present or not</b>  22 <b>present?</b>  23 A. I'm not sure. The largest part is  24 difficult. I can see a little bit of the  25 degradation bark can be sitting on the non-degraded</p>
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<p>1 <b>area larger than what is presented in this one</b>  2 <b>slide?</b>  3 A. What do you mean?  4 <b>Q. Well, this obviously depicts these</b>  5 <b>findings within this slide. This slide is</b>  6 <b>4 microns thick, and I don't know how far across.</b>  7 A. About two and a half, three  8 millimeters.  9 <b>Q. Okay. Can you tell whether this</b>  10 <b>finding is present anywhere else in the woman from</b>  11 <b>which this was explanted?</b>  12 A. Oh, it's patches. Somewhere it's  13 dilated, some areas are edematous, some are not.  14 Sometime the entire mesh is just sewed, or is shown  15 edema or dilatation. It depends, variables.  16 <b>Q. And so you're unable to say,</b>  17 <b>looking at this figure on page 39, Figure Set 6a,</b>  18 <b>whether what you've described here was causing</b>  19 <b>symptoms in this woman, correct?</b>  20 MR. ORENT: Objection.  21 THE WITNESS: Oh, I think we talked  22 about this before. Causing symptoms is a complex  23 process, and perceptions.  24 So this is abnormal mechanism, it is a  25 factor in pain mechanisms in some other areas.</p>	<p>1 bark and -- oh, I can see some of the mesh fibers  2 left here in this space.  3 <b>Q. Okay. I'm looking at the area</b>  4 <b>above that one, though. This one (indicating).</b>  5 A. Yes, it's folded and it trapped  6 some of the dye.  7 <b>Q. Now how do you know that's folded</b>  8 <b>as opposed to just mesh, part of the interstitialcy</b>  9 <b>or part of the mesh being right adjacent to it?</b>  10 A. Do you see this line, or this  11 slice, or cross-section of the fiber, it's folded  12 like this, and then there's a little bit of a dye  13 in this space, you can see it.  14 <b>Q. So what you're showing here is</b>  15 <b>vascular dilatation stasis again?</b>  16 A. Yes.  17 <b>Q. Tissue edema?</b>  18 A. Yes.  19 <b>Q. Anything else remarkable about</b>  20 <b>this slide?</b>  21 A. No.  22 <b>Q. And the top is four times</b>  23 <b>magnification, and the bottom is ten times</b>  24 <b>magnification?</b>  25 A. That's the best approximation.</p>

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<p style="text-align: right;">Page 178</p> <p>1 <b>Q. And my expert should have this</b>  2 <b>slide, correct?</b>  3 A. Yes.  4 <b>Q. Since you did 6a, 6b, 6c, does</b>  5 <b>that mean that it's from the same patient?</b>  6 A. No. They group by the feature.  7 <b>Q. Okay. So you don't look at it?</b>  8 <b>(Reporter sought clarification.)</b>  9 A. Feature. So if it's the same  10 feature, it's the same figure number, but if it's  11 different images on different pages, they are  12 labeled A, B, C, D.  13 <b>Q. What is the significance of the</b>  14 <b>edematous scar; the edema, loose scar?</b>  15 A. It's edema, the same thing we  16 discussed before. The fluid stays in it, it builds  17 up pressure and can compress the structures.  18 <b>Q. The same on page 41, 6c?</b>  19 A. That's correct.  20 <b>Q. Anything remarkable about the</b>  21 <b>image on page 41 beyond what you've described?</b>  22 A. No.  23 MR. ORENT: Counsel, I'm wondering if  24 it's a good time to take a quick lunch break?  25 THE WITNESS: It feels like it.</p>	<p style="text-align: right;">Page 180</p> <p>1 retropublic tapes as well.  2 <b>Q. And what are you showing in Figure 7a?</b>  3 A. I'm showing involvement of  4 striated muscle in the mesh.  5 <b>Q. Tell me what you mean by that.</b>  6 A. Striated muscle can be  7 incorporated right in the mesh, most likely mesh  8 migrated into the striated muscle. Or sometimes  9 it's just attached to it, so the fibrous capsule.  10 <b>Q. On the left side is the actual</b>  11 <b>slide, and on the right side you've filled in with</b>  12 <b>a red, orange and a yellow, correct?</b>  13 A. Yellow and red.  14 <b>Q. Okay. The yellow is the</b>  15 <b>polypropylene?</b>  16 A. That is correct.  17 <b>Q. And the red is what?</b>  18 A. Red is striated muscle.  19 <b>Q. All right. And you said</b>  20 <b>"involvement of striated muscle by the mesh."</b>  21 <b>This shows striated muscle adjacent to,</b>  22 <b>but not incorporated in the mesh, correct?</b>  23 A. Some parts of this incorporated,  24 sometimes it's just been fused, surface scar  25 tissue.</p>
<p style="text-align: right;">Page 179</p> <p>1 MR. THOMAS: Sure, absolutely.  2 -- OFF THE RECORD DISCUSSION --  3 -- RECESS AT 1:01 --  4 -- UPON RESUMING AT 2:11 --  5 BY MR. THOMAS:  6 <b>Q. Let's go to page 42 of your</b>  7 <b>report, please. I see you're open to it already.</b>  8 A. Um-hum.  9 <b>Q. Figure 7a says, "Involvement of</b>  10 <b>striated muscle by the mesh, H&amp;E, 4 times.</b>  11 <b>Additional TVT cases."</b>  12 <b>Again, this is a case that is not</b>  13 <b>contained within the consolidated cases?</b>  14 A. That is correct.  15 <b>Q. Can you tell whether this is</b>  16 <b>TVT or TVT-O?</b>  17 A. No.  18 <b>Q. Does the fact that it's involved</b>  19 <b>striated muscle help you at all?</b>  20 A. To a degree.  21 <b>Q. Why would that influence which</b>  22 <b>kind of mesh it is?</b>  23 A. It helps, because most frequently  24 if I see striated muscle, it's transobturator tape,  25 but occasionally I see striated muscle in</p>	<p style="text-align: right;">Page 181</p> <p>1 <b>Q. Help me. Show me where it's</b>  2 <b>incorporated in it.</b>  3 A. Well, in this case --  4 <b>Q. You're referring to the lower</b>  5 <b>right?</b>  6 A. In the lower panel, striated  7 muscle is encircling one of the mesh fibers.  8 <b>Q. Okay. What's the distance, in</b>  9 <b>four times magnification from the muscle and the</b>  10 <b>mesh?</b>  11 A. Within 1 to 2 hundred microns,  12 probably 100.  13 <b>Q. Okay. And what's the significance</b>  14 <b>of that finding to your opinions in this case?</b>  15 A. Well, if the mesh is fused with  16 the striated muscle, any contraction of the muscle  17 will tug on the mesh and prevent muscle from free  18 contraction.  19 <b>Q. And what symptoms does that create?</b>  20 A. The mesh is tugged, and you can  21 feel the mesh moving, pulling the nerves and other  22 tissues. So it's related to discomfort, feeling of  23 pressure and pain.  24 <b>Q. Once again, is it true that you</b>  25 <b>can't say by looking at the images in 7a, that this</b></p>

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<p>1 patient was experiencing pain or discomfort due to</p> <p>2 the presence of the striated muscle next to the</p> <p>3 polypropylene mesh?</p> <p>4 A. I cannot say the degree of</p> <p>5 sensation, but in this specific location, any</p> <p>6 contraction of the muscle will tug on the mesh. So</p> <p>7 there will be a degree of sensation, to what degree</p> <p>8 I cannot say.</p> <p>9 Q. All right. Anything else</p> <p>10 remarkable about the images on 42?</p> <p>11 A. No. Just striated muscle</p> <p>12 involvement by the mesh.</p> <p>13 Q. So let's go to Figure 7b on</p> <p>14 page 43. You're using a different stain here, the</p> <p>15 desmin stain.</p> <p>16 A. That is correct.</p> <p>17 Q. What is the significance of Figure</p> <p>18 Set 7b on page 43 of your report?</p> <p>19 A. Clearly, more visible in the</p> <p>20 picture.</p> <p>21 Q. What is more visible?</p> <p>22 A. Striated muscle.</p> <p>23 Q. And that's yellow in this image?</p> <p>24 A. No, brown. Brown is striated</p> <p>25 muscle.</p>	<p>1 would be a tugging, discomfort and possible pain?</p> <p>2 A. That is correct.</p> <p>3 Q. But you don't know the extent to</p> <p>4 which those may manifest themselves from this</p> <p>5 figure?</p> <p>6 A. The degree of sensation is</p> <p>7 difficult to predict, it depends on multiple</p> <p>8 factors.</p> <p>9 I mean, it's clear that in this</p> <p>10 location striated muscle contraction will be</p> <p>11 restricted, and will cause movement of the mesh.</p> <p>12 But the degree of sensation cannot be determined.</p> <p>13 Q. What about page 44? Sorry, let's</p> <p>14 go back to 43.</p> <p>15 Did that cover the remarkable findings</p> <p>16 in Figure 7b?</p> <p>17 A. No, I mean --</p> <p>18 Q. Is there anything else remarkable</p> <p>19 about this?</p> <p>20 A. We've covered everything.</p> <p>21 Q. Thank you. Figure 8a, on page 44.</p> <p>22 A. Yes.</p> <p>23 Q. "Involvement of smooth muscle by</p> <p>24 the mesh, H&amp;E, 10 times. Consolidated cases."</p> <p>25 Are you able to tell me whether this is</p>
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<p>1 Q. Brown, I'm sorry.</p> <p>2 A. Because for a non-pathologist, it</p> <p>3 would be hard to see where striated muscle is in</p> <p>4 H&amp;E section, but when we use desmin stain, it</p> <p>5 demonstrates even the presence of striated muscle.</p> <p>6 Q. I see. Are you able to tell me</p> <p>7 whether the image in 7b is from the same patient as</p> <p>8 the image in 7a?</p> <p>9 A. No, likely not.</p> <p>10 Q. Why do you say that?</p> <p>11 A. Just my recollection.</p> <p>12 Q. Are you able to tell me from what</p> <p>13 patient 7b comes from?</p> <p>14 A. I may or may not.</p> <p>15 Q. How about 7a, do you know who that</p> <p>16 came from?</p> <p>17 A. Same thing, I may or may not.</p> <p>18 Q. Okay. Tell me, please, the</p> <p>19 significance of the image in 7b.</p> <p>20 A. Now, we can see clearly that</p> <p>21 muscle is on both sides of the mesh. So the mesh</p> <p>22 is sandwiched between striated muscle, surrounded</p> <p>23 by it.</p> <p>24 Q. The same answers for 7b as 7a,</p> <p>25 that when the striated muscles touch the mesh there</p>	<p>1 a TVT or TVT-O?</p> <p>2 A. No.</p> <p>3 Q. Okay. And you can't tell me which</p> <p>4 patient it's from as you sit here?</p> <p>5 A. I can determine for this specific</p> <p>6 figures which patient it came from, because this</p> <p>7 image has been numbered by this time.</p> <p>8 Q. And can you tell right now, or do</p> <p>9 you have to consult something?</p> <p>10 A. No, no. I would have to go back</p> <p>11 and check the names of the files.</p> <p>12 Q. I see, okay.</p> <p>13 And what's the purpose of depicting the</p> <p>14 smooth muscle in this image?</p> <p>15 A. To show that smooth muscle can</p> <p>16 also be involved by the mesh.</p> <p>17 Q. Is the smooth muscle impacted in</p> <p>18 the same way as the striated muscle that you</p> <p>19 described in the last two slides?</p> <p>20 A. In a similar way, yes.</p> <p>21 Q. Okay. Is the point here to show</p> <p>22 that the smooth muscle is in close proximity to the</p> <p>23 polypropylene mesh?</p> <p>24 A. That's correct.</p> <p>25 Q. And similar to 7a and 7b, any</p>

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<p style="text-align: right;">Page 186</p> <p>1 <b>contact with polypropylene with the smooth muscle</b>  2 <b>may cause some discomfort, tugging or possible</b>  3 <b>pain?</b>  4 A. There is a little bit more to  5 smooth muscle. Because smooth muscle is present in  6 both vaginal wall and urethra and bladder.  7 So urethra and bladder have thicker  8 bundles of smooth muscle. Vaginal wall has wisps  9 of smooth muscle.  10 If mesh is in the vaginal wall, smooth  11 muscle, which is in the vaginal wall, can be either  12 attached to the scar plate. Or, if the mesh  13 migrates, it incorporates smooth muscle inside the  14 pores.  15 So if the smooth muscle of the vaginal  16 wall contracts, the mesh will interfere. So this  17 will be more of a sensation in the vagina, more  18 likely during intercourse, whether the vaginal wall  19 contracts.  20 Now, if we compare it with the smooth  21 muscle of the bladder and the urethra, it's a  22 different organ. So if mesh is interfering with  23 those bundles, they may not contract correctly. So  24 there may be interference with the function of  25 urethra and voiding, urination. And also,</p>	<p style="text-align: right;">Page 188</p> <p>1 <b>Q. Adjacent to?</b>  2 A. Moving, or pressing against this  3 bundle. It's partially compressed; you see the  4 indentation made with the mesh here.  5 <b>Q. Okay. And again, you don't know</b>  6 <b>the extent to which the situation, circumstances</b>  7 <b>described in this slide, may cause or contribute to</b>  8 <b>discomfort, tugging or pain?</b>  9 A. If it's urethral muscle, it can  10 cause urinary outflow obstruction, because it's  11 clearly pressing on this part of the muscle. So  12 it's pressing on the whole urethra.  13 <b>Q. But you don't know the extent to</b>  14 <b>which it was removed for obstruction, or why the</b>  15 <b>mesh was removed; do you?</b>  16 MR. ORENT: Objection.  17 THE WITNESS: Yeah. Again the degree  18 of the symptoms would depend on many factors. I  19 can say that this picture shows that there was a  20 degree of compression of the muscle.  21 BY MR. THOMAS:  22 <b>Q. Can you say from this slide, that</b>  23 <b>there was urinary dysfunction based upon this</b>  24 <b>slide?</b>  25 A. Complete obstruction of the</p>
<p style="text-align: right;">Page 187</p> <p>1 sensation in the area.  2 Also, you should obstruct urethra  3 through compression of it. The mesh is pressing  4 against these thick bundles, and then compresses  5 the urethra. So it's indication that position of  6 the mesh was such that it was causing urinary  7 symptoms.  8 <b>Q. Are you able to tell from Figure</b>  9 <b>8a, whether this tissue sample is from the vagina</b>  10 <b>or in the area underneath the urethra?</b>  11 A. For Figure 8a, it would be  12 difficult because it's an H&amp;E slide. If I stain it  13 with smooth muscle, then I can see exactly borders  14 and position of the muscle. Or, I can see it in  15 the microscope.  16 It's likely to be urethra, because the  17 area is more compact and there are bundles of it,  18 but I would have to look at the slide. But  19 comparing between these two applications, I would  20 favor the urethral muscle in this specific image.  21 <b>Q. And it's fair to say that the</b>  22 <b>muscle here has not yet been incorporated into the</b>  23 <b>mesh, correct?</b>  24 A. Not fully, but you can see that  25 the mesh is --</p>	<p style="text-align: right;">Page 189</p> <p>1 urinary outflow, no, I cannot say that. I mean  2 there is interference, but the degree of it is more  3 complex question.  4 <b>Q. Page 45, Figure Set 8b is the same</b>  5 <b>issue using a smooth muscle actin stain. And</b>  6 <b>because this is additional TVT cases, this is going</b>  7 <b>to be a different patient than 8a, correct?</b>  8 A. That's correct.  9 <b>Q. Is this a TVT or a TVT-O?</b>  10 A. I cannot say.  11 <b>Q. And is this the smooth muscle</b>  12 <b>stain that you referred to a few minutes ago?</b>  13 A. That's correct.  14 <b>Q. And what does the stain in Figure</b>  15 <b>Set 8b tell you?</b>  16 A. So you can see clearly that the  17 smooth muscle is in wisps. So this is the smooth  18 muscle of vaginal wall, and it became incorporated  19 into the mesh.  20 So the mesh migrated in the tissue, and  21 this part of smooth muscle became incorporated in  22 the mesh pore.  23 <b>Q. How can you tell from Figure 8b</b>  24 <b>that the mesh migrated or moved?</b>  25 A. Because it contains normal structure.</p>

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<p style="text-align: right;">Page 190</p> <p>1 <b>Q. How does this figure -- how are</b>  2 <b>you able to tell from this figure that the mesh</b>  3 <b>wasn't placed there in the first place, as opposed</b>  4 <b>to migrated or moved there?</b>  5 A. This space didn't exist before the  6 mesh was placed (indicating).  7 <b>Q. Okay. And "this space" is what</b>  8 <b>you just drew as a circle?</b>  9 A. Yes.  10 <b>Q. And what does that space represent?</b>  11 A. It's the space within the mesh.  12 So it was created in the body, when the mesh was  13 placed. When the mesh was placed, it's empty space  14 because tissue is disrupted. The mesh goes in, and  15 everything inside needs to be filled in with brand  16 new tissue. So this area was filled with tissue  17 after the mesh was placed.  18 But, we know that smooth muscle is a  19 more specialized type of tissue. It has very  20 limited ability for regeneration, so the scar which  21 can be produced. So if there is normal tissue  22 within the mesh pore, it means that it had been  23 incorporated later on, either through scar  24 contraction, which pulls normal tissue in, or  25 through mesh migration, which migrates into this</p>	<p style="text-align: right;">Page 192</p> <p>1 <b>about?</b>  2 A. That's correct.  3 <b>Q. Anything else remarkable about 45?</b>  4 A. No.  5 <b>Q. 46, Figure Set 8c.</b>  6 <b>Again, this is more smooth muscle with</b>  7 <b>smooth muscle actin stain, additional TVT cases.</b>  8 <b>Is this a third patient, do you know?</b>  9 A. This is an older case.  10 <b>Q. So is this a third patient within</b>  11 <b>this set?</b>  12 A. Most likely.  13 <b>Q. And it's an older case given the</b>  14 <b>camera that's used?</b>  15 A. Yes.  16 <b>Q. Can you tell whether it's a TVT or</b>  17 <b>TVT-O?</b>  18 A. No.  19 <b>Q. What is the significance of Figure 8c?</b>  20 A. This is a nice picture, this is  21 urethral wall.  22 <b>Q. You're talking about the muscle on</b>  23 <b>the right side of the image on the left?</b>  24 A. Yup.  25 <b>Q. Okay.</b></p>
<p style="text-align: right;">Page 191</p> <p>1 (indicating).  2 <b>Q. What types of symptoms are present</b>  3 <b>from the findings that you have in Figure Set 8b?</b>  4 A. I don't remember exact history for  5 this specific patient, but this position of smooth  6 muscle inside the mesh, is at risk for pain,  7 especially during intercourse, dyspareunia. Again,  8 the degree of these symptoms is difficult to  9 predict. But this is an abnormal position of  10 smooth muscle.  11 <b>Q. Are you suggesting that every time</b>  12 <b>this patient would have sexual intercourse, that</b>  13 <b>she experienced pain due to this condition?</b>  14 MR. ORENT: Objection.  15 THE WITNESS: How much of this will  16 contribute to her symptoms would be difficult to  17 predict. But as I said, this is an abnormal  18 position, and this abnormality provides a risk  19 factor for pain during intercourse.  20 BY MR. THOMAS:  21 <b>Q. Okay.</b>  22 A. Or just simply chronic pain.  23 <b>Q. So as we've talked about before,</b>  24 <b>this is a risk factor in conjunction with other</b>  25 <b>things that may cause the conditions you're talking</b></p>	<p style="text-align: right;">Page 193</p> <p>1 A. It's a thicker bundles of urethra,  2 and this part is vaginal wall. So this is part of  3 vaginal wall. And you can see the curve of the  4 sling was compressing urethra (indicating).  5 So this part of the sling was excised  6 with some of the urethral muscle.  7 <b>Q. What is the significance of this</b>  8 <b>finding in this figure?</b>  9 A. It shows the difference between  10 smooth muscle in the vaginal wall and smooth muscle  11 in the urethra, and the relationship of the mesh,  12 how it sits right on the muscle of the urethra.  13 <b>Q. If you look at this, as it's going</b>  14 <b>to be in-situ, is it going to look like this?</b>  15 A. Eventually it will look like this.  16 <b>Q. So this is the urethral muscle,</b>  17 <b>and I'm holding Figure 8 sideways. So this shows</b>  18 <b>how the mesh has either the U-shape or the hammock</b>  19 <b>shape underneath the urethra; correct?</b>  20 A. That is correct.  21 <b>Q. Okay. So the positioning of this</b>  22 <b>mesh is really consistent with the way it should be</b>  23 <b>placed; is that correct?</b>  24 A. It's the normal position. It's  25 not normal, intended position.</p>

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<p style="text-align: right;">Page 194</p> <p>1 <b>Q. Intended position, okay.</b></p> <p>2 <b>So what is significant about Figure 8c,</b></p> <p>3 <b>insofar as it relates to your opinions in this</b></p> <p>4 <b>case?</b></p> <p>5 A. Well, I'm demonstrating that the</p> <p>6 mesh is compressing right against urethra. And if</p> <p>7 it was more pressure, it would start migrating into</p> <p>8 urethra and sometimes I see that as well.</p> <p>9 <b>Q. When you say migrating, are you</b></p> <p>10 <b>talking about eroding into the urethra?</b></p> <p>11 A. Yes.</p> <p>12 <b>Q. Okay. There's no evidence here,</b></p> <p>13 <b>though, of evidence of erosion into the urethra,</b></p> <p>14 <b>correct?</b></p> <p>15 A. In this specific case, I don't</p> <p>16 remember.</p> <p>17 <b>Q. Well, you don't see it in the</b></p> <p>18 <b>slide. You can't offer the opinion to a reasonable</b></p> <p>19 <b>degree of medical certainty that this mesh has</b></p> <p>20 <b>eroded into the urethra here, correct?</b></p> <p>21 MR. ORENT: Objection.</p> <p>22 THE WITNESS: Not in this image. And</p> <p>23 the purpose of this different.</p> <p>24 So you can see clearly, I should have</p> <p>25 probably turned it. I should have turned it like</p>	<p style="text-align: right;">Page 196</p> <p>1 that slings can cause urinary outflow and</p> <p>2 obstruction.</p> <p>3 And with more pressure, it will start</p> <p>4 going through the muscle and become eroded. Also,</p> <p>5 it will describe the clinical phenomena.</p> <p>6 <b>Q. And when you talk about disrupting</b></p> <p>7 <b>urinary outflow, is that the same thing as</b></p> <p>8 <b>retention?</b></p> <p>9 A. Yes.</p> <p>10 <b>Q. And that's a recognized complication</b></p> <p>11 <b>from mesh placement?</b></p> <p>12 A. Yes, it is.</p> <p>13 <b>Q. Anything else remarkable about</b></p> <p>14 <b>this slide?</b></p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. THOMAS:</p> <p>18 <b>Q. Is it fair to understand that</b></p> <p>19 <b>you're not able to diagnose urinary retention based</b></p> <p>20 <b>upon this single slide, correct?</b></p> <p>21 A. Retention is a symptom, as we've</p> <p>22 discussed before, symptoms are caused by multiple</p> <p>23 factors together, so...</p> <p>24 <b>Q. Answer my question. Based on this</b></p> <p>25 <b>slide alone, you can't make that finding?</b></p>
<p style="text-align: right;">Page 195</p> <p>1 this (indicating). And this would demonstrate that</p> <p>2 with more pressure, it would start migrating; in</p> <p>3 this specific case, it didn't.</p> <p>4 BY MR. THOMAS:</p> <p>5 <b>Q. Isn't this supposed to be right</b></p> <p>6 <b>underneath the urethra in order to control the</b></p> <p>7 <b>urine flow?</b></p> <p>8 A. Yes, but I mean --</p> <p>9 <b>Q. Is this not placed properly?</b></p> <p>10 MR. ORENT: Objection.</p> <p>11 THE WITNESS: I wouldn't go and I</p> <p>12 cannot testify exactly for placement.</p> <p>13 To me, as a pathologist, I examine what</p> <p>14 is abnormal and what can cause symptoms.</p> <p>15 So if there are specific requirements</p> <p>16 for placement or positioning, it would be a</p> <p>17 clinical question.</p> <p>18 BY MR. THOMAS:</p> <p>19 <b>Q. Okay.</b></p> <p>20 A. So to me, this position, right</p> <p>21 against smooth muscle of urethra, indicates that</p> <p>22 sling is compressing against urethra directly.</p> <p>23 So, with extra pressure, you can</p> <p>24 collapse or compress urethra and cause urinary</p> <p>25 outflow. And this is repeated in medical histories</p>	<p style="text-align: right;">Page 197</p> <p>1 A. You can say that this position</p> <p>2 creates a risk for obstruction.</p> <p>3 <b>Q. Yeah.</b></p> <p>4 A. And a degree of compression of the</p> <p>5 urethra.</p> <p>6 <b>Q. But like everything else, that's a</b></p> <p>7 <b>risk factor that you'd have to combine with other</b></p> <p>8 <b>things to determine whether, and to what extent</b></p> <p>9 <b>this could cause any problems in her, right?</b></p> <p>10 MR. ORENT: Objection.</p> <p>11 THE WITNESS: Not necessarily. It may</p> <p>12 not need other factors. It may cause symptom on</p> <p>13 its own. But the degree of the symptom is clinical</p> <p>14 presentation.</p> <p>15 BY MR. THOMAS:</p> <p>16 <b>Q. And you don't know what that</b></p> <p>17 <b>clinical presentation is as you sit here today?</b></p> <p>18 A. That's correct.</p> <p>19 <b>Q. Page 47, Figure 8d. This is,</b></p> <p>20 <b>"Innervation within the mesh and between the mucosa</b></p> <p>21 <b>and the mesh. Also, images of muscle movement</b></p> <p>22 <b>involvement by the mesh." And this is a</b></p> <p>23 <b>publication?</b></p> <p>24 A. That's correct.</p> <p>25 <b>Q. Do you know what kinds of mesh are</b></p>

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<p>1 <b>involved here?</b></p> <p>2 A. I don't remember. I think two of</p> <p>3 these images are from TVT or TVT-O. And two of</p> <p>4 these images are from different mesh.</p> <p>5 <b>Q. Which ones are from TVT or TVT-O?</b></p> <p>6 A. I don't remember now. I would</p> <p>7 have to sort of do matching.</p> <p>8 <b>Q. Okay. What other manufacturers</b></p> <p>9 <b>did you look at?</b></p> <p>10 A. AMS, Boston Scientific, Bard.</p> <p>11 <b>Q. And do you know which of those</b></p> <p>12 <b>manufacturers are depicted in this image?</b></p> <p>13 A. No, I know for sure that there's</p> <p>14 at least one TVT mesh here.</p> <p>15 <b>Q. At least one?</b></p> <p>16 A. At least one. I don't remember --</p> <p>17 <b>Q. Do you know whether it was a TVT</b></p> <p>18 <b>or a TVT-O?</b></p> <p>19 A. No.</p> <p>20 <b>Q. Okay. And what is the purpose of</b></p> <p>21 <b>this image?</b></p> <p>22 A. It demonstrates same smooth muscle</p> <p>23 involvement.</p> <p>24 <b>Q. Are you able to tell -- as I</b></p> <p>25 <b>understand the smooth muscle is either going to be</b></p>	<p>1 two or both (indicating).</p> <p>2 BY MR. THOMAS:</p> <p>3 <b>Q. Okay. C and D, correct?</b></p> <p>4 A. C and D. That is my recollection.</p> <p>5 <b>Q. What is it about those images that</b></p> <p>6 <b>cause you to believe it's an Ethicon TVT or TVT-O?</b></p> <p>7 A. Oh, maybe not. Wait a second.</p> <p>8 (Witness reviews document).</p> <p>9 Sorry. I have to retry this. I don't</p> <p>10 remember which exactly are TVT or TVT-O. It could</p> <p>11 be one of these images in one of these.</p> <p>12 <b>Q. It could be any one of the four?</b></p> <p>13 MR. ORENT: Objection.</p> <p>14 THE WITNESS: Yes, I would have to go</p> <p>15 back and check.</p> <p>16 BY MR. THOMAS:</p> <p>17 <b>Q. Now this is smooth muscle; is that</b></p> <p>18 <b>what you're saying?</b></p> <p>19 A. These are smooth muscle.</p> <p>20 <b>Q. In A, B, C and D?</b></p> <p>21 A. No. Figure A shows neurovascular</p> <p>22 bundle in the pore, we saw similar images before</p> <p>23 that.</p> <p>24 Figure B shows innervation between</p> <p>25 sling and mucosa.</p>
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<p>1 <b>in the vagina or around the urethra, correct?</b></p> <p>2 A. That's correct.</p> <p>3 <b>Q. Are you able to tell in Figure 8</b></p> <p>4 <b>whether this is the vagina or the urethra?</b></p> <p>5 A. Let me see, because the pictures</p> <p>6 are cropped to a degree.</p> <p>7 <b>Q. They're "cropped", did you say?</b></p> <p>8 A. Cropped, yes. So I need the</p> <p>9 larger pictures to -- let me see.</p> <p>10 Maybe it's described in the caption.</p> <p>11 (Witness reviews document.)</p> <p>12 Just representative image. From what I</p> <p>13 see, but it's not 100 percent, it may not be</p> <p>14 100 percent correct.</p> <p>15 C, would reflect urethral muscle. And</p> <p>16 D would reflect vaginal muscle. But I'm not sure,</p> <p>17 because most of the structures are cropped. It</p> <p>18 just describes the fact that the mesh can</p> <p>19 incorporate smooth muscle, from either origin.</p> <p>20 <b>Q. And just so we're clear. You're</b></p> <p>21 <b>pretty sure that one of these is a TVT or a TVT-O,</b></p> <p>22 <b>but you don't know which of the four figures in</b></p> <p>23 <b>Figure Set 8d is a Johnson &amp; Johnson product?</b></p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: It would be either these</p>	<p>1 Figure C -- (witness reviews document.)</p> <p>2 <b>Q. Are you reading the text now?</b></p> <p>3 A. Yes. So Figure C shows striated</p> <p>4 muscle.</p> <p>5 And Figure D, shows smooth muscle</p> <p>6 unspecified, either from vagina or urethra.</p> <p>7 <b>Q. Okay. And is the purpose of this</b></p> <p>8 <b>image just to show the innervation of the mesh in</b></p> <p>9 <b>general?</b></p> <p>10 A. Well, the purpose of the image is</p> <p>11 to show all these pictures together. And I</p> <p>12 included it because I knew that at least one</p> <p>13 contains TVT or TVT-O, it is a supplementary</p> <p>14 picture.</p> <p>15 <b>Q. Anything else significance for the</b></p> <p>16 <b>figures on page 47?</b></p> <p>17 A. No.</p> <p>18 <b>Q. Page 48, Figure Set 9a. "Arterial</b></p> <p>19 <b>obliteration in the mesh scar plate, H&amp;E 10 times.</b></p> <p>20 <b>Consolidated cases."</b></p> <p>21 <b>This obviously is from one of the</b></p> <p>22 <b>plaintiffs in the consolidated cases.</b></p> <p>23 A. Yes.</p> <p>24 <b>Q. And you've indicated on the image</b></p> <p>25 <b>an obliterated artery. How can you -- what is it</b></p>

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<p>1 about this image that tells you that this artery is</p> <p>2 obliterated?</p> <p>3 A. The lumen is collapsed.</p> <p>4 <b>Q. The lumen is collapsed?</b></p> <p>5 A. Yes. The arterial wall is</p> <p>6 degenerated, so clearly non-functional.</p> <p>7 <b>Q. And what does it mean to have an</b></p> <p>8 <b>obliterated artery?</b></p> <p>9 A. It means that there is an area in</p> <p>10 the body which had insufficient or disrupted blood</p> <p>11 supply.</p> <p>12 <b>Q. Okay. When you say "insufficient</b></p> <p>13 <b>or disrupted", it can be disrupted without being</b></p> <p>14 <b>insufficient; can't it?</b></p> <p>15 A. That's correct. There might be a</p> <p>16 collateral circulation sufficient to supply.</p> <p>17 <b>Q. And you're not able to tell from</b></p> <p>18 <b>looking at this image in Figure Set 9a, that if</b></p> <p>19 <b>this is an obliterated artery, that it has any</b></p> <p>20 <b>clinical impact on the patient, correct?</b></p> <p>21 MR. ORENT: Objection.</p> <p>22 THE WITNESS: Again, could have had</p> <p>23 only short-term impact, could have had longer term</p> <p>24 impact. Short term would be necrosis, right after</p> <p>25 the obliteration, or thrombosis, it's like heart</p>	<p>1 MR. ORENT: Objection.</p> <p>2 THE WITNESS: Not in this area.</p> <p>3 BY MR. THOMAS:</p> <p>4 <b>Q. Okay.</b></p> <p>5 A. But it tells us that somewhere</p> <p>6 else beyond this square picture, there was damage</p> <p>7 for the tissue.</p> <p>8 <b>Q. There was or may be?</b></p> <p>9 A. There was.</p> <p>10 <b>Q. Okay.</b></p> <p>11 A. The degree of it is difficult to</p> <p>12 determine. But there was.</p> <p>13 <b>Q. You'd have to see the tissue in</b></p> <p>14 <b>order to make that evaluation, correct?</b></p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. THOMAS:</p> <p>18 <b>Q. Where is the mesh in Figure 9a?</b></p> <p>19 A. Somewhere beyond it.</p> <p>20 <b>Q. It's not in the slide?</b></p> <p>21 A. Maybe right at the corners, I</p> <p>22 don't know.</p> <p>23 <b>Q. But you didn't capture any mesh in</b></p> <p>24 <b>the slide on 9a?</b></p> <p>25 A. I didn't crop it in.</p>
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<p>1 attack.</p> <p>2 And then long-term would be scarring</p> <p>3 and fibrosis. The same thing as a heart, people</p> <p>4 who have insufficient cardiac output. If heart</p> <p>5 muscle doesn't work as well as before the infarct,</p> <p>6 so the same thing here, it would be a short term,</p> <p>7 shortly symptoms or changes in the body. And then</p> <p>8 longer term. Longer term would be caused more</p> <p>9 fibrosis.</p> <p>10 BY MR. THOMAS:</p> <p>11 <b>Q. And longer term there may or may</b></p> <p>12 <b>not be a problem, correct?</b></p> <p>13 A. You mean how they would translate</p> <p>14 into clinical symptoms?</p> <p>15 <b>Q. Yes.</b></p> <p>16 A. The degree of translation into</p> <p>17 clinical symptoms is more a complex process.</p> <p>18 <b>Q. Okay. Is there necrosis in this</b></p> <p>19 <b>image?</b></p> <p>20 A. No. Because artery has supplied</p> <p>21 the blood to somewhere else further down, so...</p> <p>22 <b>Q. Okay. So given your finding of an</b></p> <p>23 <b>obliterated artery, there are no clinical symptoms</b></p> <p>24 <b>manifested in this image, at this time that you can</b></p> <p>25 <b>point to, correct?</b></p>	<p>1 <b>Q. Let's go to page 49, Figure Set 9b.</b></p> <p>2 A. Yes.</p> <p>3 <b>Q. It says, "Examples of capillary</b></p> <p>4 <b>thrombosis in the mesh scar plate."</b></p> <p>5 <b>What is "capillary thrombosis"?</b></p> <p>6 A. When there are small thrombi</p> <p>7 formed in the capillaries.</p> <p>8 <b>Q. What is the significance of</b></p> <p>9 <b>capillary thrombosis in the mesh scar plate?</b></p> <p>10 A. The same as for arteries, just on</p> <p>11 a small scale. So there's interruption of blood</p> <p>12 supply in the smaller area. Artery can cover large</p> <p>13 area, capillaries are covering small.</p> <p>14 <b>Q. Is there anything about what you</b></p> <p>15 <b>see in Figure Set 9b, that would tell you that this</b></p> <p>16 <b>patient is experiencing any clinical symptoms?</b></p> <p>17 A. Again, the degree of manifestation</p> <p>18 of this finding would be difficult to determine.</p> <p>19 <b>Q. It could be nothing?</b></p> <p>20 A. May not be clinically apparent.</p> <p>21 <b>Q. And is this a single plaintiff or</b></p> <p>22 <b>is it two different plaintiffs? It says,</b></p> <p>23 <b>"additional TVT cases." I can't tell if it's one</b></p> <p>24 <b>patient or two.</b></p> <p>25 A. I think it's from the same patient.</p>

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<p>1 <b>Q. Is it a TVT or TVT-O?</b></p> <p>2 A. I think it was the Edwards case.</p> <p>3 That's as far as I can recollect.</p> <p>4 <b>Q. Okay. Is there any mesh in Figure</b></p> <p>5 <b>Set 9b?</b></p> <p>6 A. Right there (indicating).</p> <p>7 <b>Q. So that's on the lower left, okay.</b></p> <p>8 <b>Is there any mesh in the image above?</b></p> <p>9 A. Not in the image. It was probably</p> <p>10 right beside it.</p> <p>11 <b>Q. Okay. Let's go to Figure Set 10a</b></p> <p>12 <b>on page 50. It says, "TVT sling curled into a roll</b></p> <p>13 <b>cross-section through parallel walls. H&amp;E stain</b></p> <p>14 <b>2.5 power magnification. Consolidated cases."</b></p> <p>15 <b>This shows a piece of curled mesh,</b></p> <p>16 <b>doesn't it?</b></p> <p>17 A. That is correct.</p> <p>18 <b>Q. And this is the curled mesh that</b></p> <p>19 <b>you talked about before when you place it in</b></p> <p>20 <b>formalin that it will curl over on itself, correct?</b></p> <p>21 <b>When it's placed in formalin?</b></p> <p>22 A. Did I say that it curls in</p> <p>23 formalin? I said that mesh, which is curled in</p> <p>24 scar tissue, curled in the body.</p> <p>25 <b>Q. I see. So you believe that this</b></p>	<p>1 <b>obviously has been pulled away from the slide,</b></p> <p>2 <b>correct?</b></p> <p>3 A. That's correct.</p> <p>4 <b>Q. That's polypropylene?</b></p> <p>5 A. That's correct.</p> <p>6 <b>Q. Let's go to set 10b. Is set 10b</b></p> <p>7 <b>from the same patient or a different patient?</b></p> <p>8 A. I suspect it is the same patient.</p> <p>9 <b>Q. Do you know?</b></p> <p>10 A. Not with 100 percent certainty.</p> <p>11 But I think it is. It's just a different part the</p> <p>12 of the same curled mesh.</p> <p>13 <b>Q. Okay. And does Figure Set</b></p> <p>14 <b>10b show anything new beyond what you've showed in</b></p> <p>15 <b>10a, or is it the same?</b></p> <p>16 A. It's the same, just tighter roll.</p> <p>17 <b>Q. And if you look at the images at</b></p> <p>18 <b>the top, there's a blue line coming out of the top</b></p> <p>19 <b>right, and that's a polypropylene artifact?</b></p> <p>20 A. Displaced polypropylene fibers.</p> <p>21 You can also see dilated vascular channels.</p> <p>22 (Reporter sought clarification.)</p> <p>23 A. So in this area, there is vascular</p> <p>24 dilation.</p> <p>25 <b>Q. Can you tell from these images,</b></p>
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<p>1 <b>curled in the body?</b></p> <p>2 A. Yes.</p> <p>3 <b>Q. And on what basis do you believe</b></p> <p>4 <b>that?</b></p> <p>5 A. Because that curl shape is</p> <p>6 immobilized within the scar tissue, it's</p> <p>7 incorporated in the scar tissue, in this shape.</p> <p>8 <b>Q. Okay. Anything other than the</b></p> <p>9 <b>curling phenomena that you've just described as the</b></p> <p>10 <b>purpose of Figure Set 10a?</b></p> <p>11 A. Curling phenomena, scarring, it's</p> <p>12 all encased in scar tissue.</p> <p>13 <b>Q. Okay.</b></p> <p>14 A. That's about it.</p> <p>15 <b>Q. Okay. And at the top where we see</b></p> <p>16 <b>the blue, those are going to be artifacts?</b></p> <p>17 A. No. The blue ones are</p> <p>18 cross-sections of the blue filaments.</p> <p>19 <b>Q. I should have said, in places</b></p> <p>20 <b>where they don't fill the holes?</b></p> <p>21 A. It can't be clear filament.</p> <p>22 Because remember, half of the fibers in the sling</p> <p>23 are blue, half of them are clear.</p> <p>24 <b>Q. Okay. Let's look at the top, off</b></p> <p>25 <b>of the slide there is a blue fragment. That</b></p>	<p>1 <b>10a and 10b, whether this mesh caused any symptoms</b></p> <p>2 <b>in the patient when it was implanted?</b></p> <p>3 MR. ORENT: Objection.</p> <p>4 THE WITNESS: My answer is the same.</p> <p>5 Clinical symptoms is a multifactorial, complex</p> <p>6 phenomena.</p> <p>7 BY MR. THOMAS:</p> <p>8 <b>Q. This is a risk factor?</b></p> <p>9 A. No, this is not a risk factor,</p> <p>10 this is a mechanism, how the complications occur.</p> <p>11 But then there is a patient in between</p> <p>12 who feels the symptoms, and the body however reacts</p> <p>13 and so forth. But in this case, the mesh is</p> <p>14 rolled, so the pressure is distributed in a small</p> <p>15 area.</p> <p>16 The probability that it will compress</p> <p>17 urethra is higher, because if it was flat, it would</p> <p>18 have much larger distribution of pressure.</p> <p>19 <b>Q. So is the risks from this curl</b></p> <p>20 <b>mesh compression against the urethra and urinary</b></p> <p>21 <b>retention?</b></p> <p>22 A. Yes, one of those.</p> <p>23 <b>Q. Do you know whether this patient</b></p> <p>24 <b>had urinary retention?</b></p> <p>25 MR. ORENT: Objection.</p>

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<p style="text-align: right;">Page 210</p> <p>1 THE WITNESS: I don't remember now.</p> <p>2 Because my purpose for this report was to actually</p> <p>3 show these things which can happen, and the</p> <p>4 pathological changes which happen after mesh</p> <p>5 placement.</p> <p>6 And, symptoms which can factor in.</p> <p>7 BY MR. THOMAS:</p> <p>8 <b>Q. Okay.</b></p> <p>9 A. But I wasn't working on specific</p> <p>10 connection between this pathological change, caused</p> <p>11 that symptom in this specific patient.</p> <p>12 <b>Q. Okay. Anything else remarkable</b></p> <p>13 <b>about the images on 50 and 51?</b></p> <p>14 A. No.</p> <p>15 <b>Q. Go to page 52. And you get</b></p> <p>16 <b>"Neurovascular bundle within curled mesh, four</b></p> <p>17 <b>times magnification. Consolidated cases."</b></p> <p>18 <b>Is this a different patient than was</b></p> <p>19 <b>depicted in 10a and 10b?</b></p> <p>20 A. One of these, because I say that</p> <p>21 it's curled mesh --</p> <p>22 (Witness reviews document).</p> <p>23 So likely it was one of these two.</p> <p>24 <b>Q. I think you told me -- well, maybe</b></p> <p>25 <b>I didn't hear this right. I thought you told me</b></p>	<p style="text-align: right;">Page 212</p> <p>1 talk about flat mesh, it's sort of third dimension.</p> <p>2 So compartments are within the thickness of the</p> <p>3 mesh. But when it curls, it creates secondary</p> <p>4 compartment. Compartment which is encircled by the</p> <p>5 mesh or between the folds.</p> <p>6 <b>Q. Anything that you can see in</b></p> <p>7 <b>Figure 10c, on page 52 that is abnormal or</b></p> <p>8 <b>symptomatic about that neurovascular bundle, other</b></p> <p>9 <b>than its presence in the scar tissue?</b></p> <p>10 A. It's abnormal location.</p> <p>11 <b>Q. It's simply that, the abnormal</b></p> <p>12 <b>location?</b></p> <p>13 A. Yes.</p> <p>14 <b>Q. Anything else?</b></p> <p>15 A. The surroundings are abnormal.</p> <p>16 <b>Q. Okay. Anything else remarkable</b></p> <p>17 <b>about that image?</b></p> <p>18 A. No.</p> <p>19 <b>Q. Let's go to page 53, section 10d.</b></p> <p>20 <b>This is, "A twisted TVT sling" from additional TVT</b></p> <p>21 <b>cases."</b></p> <p>22 <b>So this is one of your older cases,</b></p> <p>23 <b>correct?</b></p> <p>24 A. Yeah. Earlier or concurrent.</p> <p>25 <b>Q. Is this a TVT or TVT-O?</b></p>
<p style="text-align: right;">Page 211</p> <p>1 <b>that A and B were from the same person?</b></p> <p>2 A. Most likely.</p> <p>3 <b>Q. Do you know?</b></p> <p>4 A. I can tell you, but not right now.</p> <p>5 I can just check the name of the files.</p> <p>6 <b>Q. And do you think that 10c, is the</b></p> <p>7 <b>same or different person?</b></p> <p>8 A. Most likely it is the same person,</p> <p>9 or one of the two. It could all be from one</p> <p>10 patient, it could be from two patients.</p> <p>11 <b>Q. Okay. In the top part on 10c, on</b></p> <p>12 <b>page 52, you have a displaced piece of</b></p> <p>13 <b>polypropylene?</b></p> <p>14 A. Yes.</p> <p>15 <b>Q. And what's the significance of</b></p> <p>16 <b>identifying this neurovascular bundle in the</b></p> <p>17 <b>figure?</b></p> <p>18 A. As before, we were talking about</p> <p>19 entrapment of the neurovascular bundle before. But</p> <p>20 in this case, it's not just in pore. It goes in</p> <p>21 the pore, and became entrapped in the curls.</p> <p>22 So it's in between two layers of the</p> <p>23 mesh right inside the curl. So it's secondary type</p> <p>24 of compartment. Because before we're talking about</p> <p>25 compartmentalizing nature of the mesh, and then we</p>	<p style="text-align: right;">Page 213</p> <p>1 A. I don't know.</p> <p>2 <b>Q. What is the significance of what</b></p> <p>3 <b>you've done in Figure 10d?</b></p> <p>4 A. It shows that the mesh just</p> <p>5 curled, and also twisted. To get the shape like</p> <p>6 this out of flat tape, it has to curl and then one</p> <p>7 end is twist.</p> <p>8 Just think about it, how they put these</p> <p>9 sections in this shape. So one end like this, and</p> <p>10 the other one is probably like that (indicating).</p> <p>11 Or maybe like this (indicating).</p> <p>12 <b>Q. Okay. Does that happen by</b></p> <p>13 <b>placement, or by migration in the body, or do you</b></p> <p>14 <b>know?</b></p> <p>15 A. It's hard to figure out if you can</p> <p>16 place it like this.</p> <p>17 <b>Q. Do you know?</b></p> <p>18 A. I don't know. One thing I can</p> <p>19 tell you, this shape was formed in the body and</p> <p>20 then it became incorporated in scar tissue like</p> <p>21 this.</p> <p>22 <b>Q. But you don't know whether that</b></p> <p>23 <b>happened on placement or in some other way?</b></p> <p>24 A. No.</p> <p>25 <b>Q. Okay. Now, in Figure 2 and</b></p>

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<p style="text-align: right;">Page 214</p> <p>1 <b>Figure 3, you show different images of the yellow.</b></p> <p>2 <b>What's the purpose of doing gradations of the</b></p> <p>3 <b>yellow?</b></p> <p>4 A. Well, this shows the planes of the</p> <p>5 mesh. Just to help you to understand that we're</p> <p>6 talking about the mesh which twisted.</p> <p>7 <b>Q. Okay. Figure 10e is explanted</b></p> <p>8 <b>mesh. This has been in formalin, correct?</b></p> <p>9 A. Yes. I believe it was in</p> <p>10 formalin.</p> <p>11 <b>Q. Okay. And no attempt to clean it</b></p> <p>12 <b>at all, correct?</b></p> <p>13 A. That is correct.</p> <p>14 <b>Q. And the purpose here is to show</b></p> <p>15 <b>what you believe to be the curling of the mesh?</b></p> <p>16 A. Well, it's not what I believe. I</p> <p>17 observe curling. It's hard to show in the picture,</p> <p>18 but when you look at it with just magnifying glass</p> <p>19 or if you have good eyes, you can see that the mesh</p> <p>20 is curled up and then it's all filled with scar</p> <p>21 tissue.</p> <p>22 <b>Q. Is the purpose of this just to</b></p> <p>23 <b>show the simple curling, or are you trying to show</b></p> <p>24 <b>something beyond other than that?</b></p> <p>25 A. No, just curling. And that the</p>	<p style="text-align: right;">Page 216</p> <p>1 <b>Q. Is it TVT or TVT-O?</b></p> <p>2 A. I don't know.</p> <p>3 <b>Q. Does the AMS figure have any</b></p> <p>4 <b>relevance to your discussion in this case?</b></p> <p>5 A. Not necessarily, no.</p> <p>6 <b>Q. Okay. Tell me what is significant</b></p> <p>7 <b>to you about the TVT in part B of set 10f?</b></p> <p>8 A. See, the images which were taken</p> <p>9 from publications were not cropped, so I don't</p> <p>10 remove any panels. So in this image, I think I had</p> <p>11 a TVT, I provided the entire --</p> <p>12 <b>Q. I understand, that's okay.</b></p> <p>13 A. So in this case I can tell exactly</p> <p>14 this is TVT, and this is a different manufacturer.</p> <p>15 <b>Q. All right. So what is the</b></p> <p>16 <b>significance of slide B?</b></p> <p>17 A. It's curled, it's roped. You can</p> <p>18 see it's not tightly -- it's not flat. It's</p> <p>19 tightly curled.</p> <p>20 <b>Q. Can you tell whether it was placed</b></p> <p>21 <b>that way or whether that happened after placement?</b></p> <p>22 MR. ORENT: Objection.</p> <p>23 THE WITNESS: I can't say. The only</p> <p>24 thing I can say is that it happened in the body.</p> <p>25</p>
<p style="text-align: right;">Page 215</p> <p>1 curled shape is actually filled with scar tissue.</p> <p>2 It's not formalin, as you'd like to say, causing</p> <p>3 the curling. It was removed from the body in that</p> <p>4 shape.</p> <p>5 <b>Q. Can you tell whether, assuming</b></p> <p>6 <b>this is curled in the body, whether it was curled</b></p> <p>7 <b>upon placement or curled after placement?</b></p> <p>8 A. The only thing I can say, it can</p> <p>9 happen, and it happened.</p> <p>10 <b>Q. Okay. But you don't know whether</b></p> <p>11 <b>it happened during placement or after placement?</b></p> <p>12 MR. ORENT: Objection.</p> <p>13 THE WITNESS: I don't know.</p> <p>14 BY MR. THOMAS:</p> <p>15 <b>Q. If you go to page 55, Figures A</b></p> <p>16 <b>and B, set 10f. "A TVT sling with curled edges.</b></p> <p>17 <b>Right sling is TVT."</b></p> <p>18 <b>Are these two different slings or one;</b></p> <p>19 <b>do you know?</b></p> <p>20 A. These are two different slings,</p> <p>21 this is AMS, this one I remember.</p> <p>22 <b>Q. AMS is on the left?</b></p> <p>23 A. Yes.</p> <p>24 <b>Q. And TVT is on the right?</b></p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 217</p> <p>1 BY MR. THOMAS:</p> <p>2 <b>Q. Okay. Anything else remarkable</b></p> <p>3 <b>about 10f on page 55?</b></p> <p>4 A. No, just roping.</p> <p>5 <b>Q. Page 56, you have Figure Set</b></p> <p>6 <b>10f again. Is that a typo, or is that the same</b></p> <p>7 <b>mesh? It looks like a different mesh, it looks</b></p> <p>8 <b>like one of yours.</b></p> <p>9 A. It's a typo.</p> <p>10 <b>Q. So this would be 10f --</b></p> <p>11 A. No, it should be 10d.</p> <p>12 <b>Q. 10d?</b></p> <p>13 A. I think it's the same specimen as</p> <p>14 10e.</p> <p>15 <b>Q. Okay.</b></p> <p>16 A. The same case, I believe. So this</p> <p>17 case took two pieces. One piece was rolled like</p> <p>18 this, like 10e.</p> <p>19 <b>Q. Okay.</b></p> <p>20 A. And the second piece was flat</p> <p>21 area. Sometimes one piece, especially if it's</p> <p>22 heat-treated doesn't curl. So there is a segment</p> <p>23 of mesh --</p> <p>24 <b>Q. What do you mean heat-treated,</b></p> <p>25 <b>during removal?</b></p>

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<p style="text-align: right;">Page 218</p> <p>1 A. No, during manufacturing.</p> <p>2 <b>Q. Are you talking about heat-treated</b></p> <p>3 <b>as in laser cut?</b></p> <p>4 A. No, the entire surface is</p> <p>5 heat-treated, not just edges.</p> <p>6 <b>Q. And so what impact -- I didn't see</b></p> <p>7 <b>it anywhere in your report, that heat somehow in</b></p> <p>8 <b>the manufacturing process will impact the ability</b></p> <p>9 <b>of the mesh to lay flat in the body?</b></p> <p>10 A. It doesn't curl -- oh, doesn't</p> <p>11 curl as much.</p> <p>12 <b>Q. Okay.</b></p> <p>13 A. It's more stable structure because</p> <p>14 fibers are welded together, or to a degree</p> <p>15 connected together.</p> <p>16 <b>Q. Okay.</b></p> <p>17 A. I know that some of the tapes --</p> <p>18 <b>Q. Some other manufacturers?</b></p> <p>19 A. Other manufacturers, middle</p> <p>20 portion is heat-treated.</p> <p>21 <b>Q. Okay. So did Boston Scientific</b></p> <p>22 <b>mention it?</b></p> <p>23 A. I don't know.</p> <p>24 <b>Q. It's all right.</b></p> <p>25 A. I don't remember now. I mean some</p>	<p style="text-align: right;">Page 220</p> <p>1 <b>TVT cases?</b></p> <p>2 A. Yes.</p> <p>3 <b>Q. Has this been produced in a report</b></p> <p>4 <b>somewhere? I've never seen this image in a case</b></p> <p>5 <b>anywhere, I'm just curious to know if it's been</b></p> <p>6 <b>published in a report someplace.</b></p> <p>7 A. I don't want to disclose that if</p> <p>8 it has not been produced, so it have been produced.</p> <p>9 <b>Q. Let me ask you this. Here is why</b></p> <p>10 <b>I ask: Generally, as you know, at least with</b></p> <p>11 <b>Ethicon, we divide these meshes before any work is</b></p> <p>12 <b>done on them.</b></p> <p>13 <b>Did you divide this mesh with Ethicon</b></p> <p>14 <b>before you did this work on 10f?</b></p> <p>15 A. It could be that was divided with</p> <p>16 your expert, so we were taking pictures together.</p> <p>17 <b>Q. Okay. Well maybe that's right.</b></p> <p>18 A. I think it was the case. Now I</p> <p>19 can vaguely remember the issue because we were</p> <p>20 discussing how we're going to cut this diagonal or</p> <p>21 cut it --</p> <p>22 <b>Q. I see.</b></p> <p>23 A. And so I remember him standing</p> <p>24 beside me, and I was taking those pictures.</p> <p>25 <b>Q. I see.</b></p>
<p style="text-align: right;">Page 219</p> <p>1 of them were coming out first, with no heat</p> <p>2 treatment, and then later on they became</p> <p>3 heat-treated.</p> <p>4 So some portions don't curl because of</p> <p>5 heat treatment, or just don't curl because of other</p> <p>6 factors. So in this specific case, there was a</p> <p>7 segment of the sling removed, and it was curled.</p> <p>8 And in another segment of the sling removed and it</p> <p>9 remained flat in the body.</p> <p>10 <b>Q. Okay. Do you know why?</b></p> <p>11 A. No, I don't know. One of the</p> <p>12 reasons can be heat treatment.</p> <p>13 <b>Q. It could also be placement?</b></p> <p>14 A. It could also be placement or</p> <p>15 location.</p> <p>16 <b>Q. And what is the purpose of the red</b></p> <p>17 <b>and the yellow on the image on 10f on page 56?</b></p> <p>18 A. It just demonstrates how flat</p> <p>19 section of the mesh looks, and how a curled section</p> <p>20 of the mesh looks. Because here, cross-section,</p> <p>21 this mesh.</p> <p>22 <b>Q. Yes?</b></p> <p>23 A. And then it came on histological</p> <p>24 sections like this.</p> <p>25 <b>Q. Is this from a case, additional</b></p>	<p style="text-align: right;">Page 221</p> <p>1 A. I took this picture, then this</p> <p>2 picture, then we probably have similar pictures</p> <p>3 from him.</p> <p>4 <b>Q. And I apologize, I've been asking</b></p> <p>5 <b>this question a lot, and I don't know if I've asked</b></p> <p>6 <b>you about this slide, so if I have, I apologize.</b></p> <p>7 <b>You don't know whether the curling</b></p> <p>8 <b>depicted in 10f, on page 56 occurred during</b></p> <p>9 <b>placement or after placement, do you?</b></p> <p>10 A. No, I don't.</p> <p>11 MR. ORENT: Objection.</p> <p>12 BY MR. THOMAS:</p> <p>13 <b>Q. Page 57, Figure Set 10g. "A TVT</b></p> <p>14 <b>sling with curled edges." Is this a different TVT</b></p> <p>15 <b>than the ones we've looked at?</b></p> <p>16 A. I think these are the pictures of</p> <p>17 the same case. Again, that is my recollection, I'm</p> <p>18 not 100 percent sure, but I think.</p> <p>19 <b>Q. Do you know if this is a TVT or a</b></p> <p>20 <b>TVT-O?</b></p> <p>21 A. No.</p> <p>22 <b>Q. Are you trying to show anything by</b></p> <p>23 <b>these images on 10g other than a different</b></p> <p>24 <b>depiction of what's in 10f?</b></p> <p>25 A. Well, no. This just shows the</p>

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<p style="text-align: right;">Page 222</p> <p>1 curling state, this cross-section (indicating).</p> <p>2 <b>Q. Okay. So it's your best</b></p> <p>3 <b>recollection that the images in 10e, 10f and 10g,</b></p> <p>4 <b>are from the same mesh, same patient?</b></p> <p>5 A. Yes, likely than not, these are</p> <p>6 all from the same patient.</p> <p>7 <b>Q. But you're not sure?</b></p> <p>8 A. No. As I said, the purpose of</p> <p>9 this report was to analyze the device as a whole,</p> <p>10 not the individual patients.</p> <p>11 <b>Q. 10h: "TVT sling with curled</b></p> <p>12 <b>edges. Additional TVT cases"?</b></p> <p>13 A. Yes.</p> <p>14 <b>Q. Do you know where -- is this a new</b></p> <p>15 <b>patient; do you know?</b></p> <p>16 A. It's older pictures, taken by old</p> <p>17 camera.</p> <p>18 <b>Q. Do you know whether this is a</b></p> <p>19 <b>TVT or TVT-O?</b></p> <p>20 A. No.</p> <p>21 <b>Q. What is the purpose of this image?</b></p> <p>22 A. It show the cross-section of the</p> <p>23 curl. And you can see it clearly, the whole field</p> <p>24 is scar tissue. This indicates that this curl</p> <p>25 shape was formed in the body and then the scar</p>	<p style="text-align: right;">Page 224</p> <p>1 is inside the roll of the curled tape.</p> <p>2 <b>Q. And is there anything about the</b></p> <p>3 <b>depiction in the neurovascular bundle in set 10i on</b></p> <p>4 <b>page 59 that is irregular or abnormal other than</b></p> <p>5 <b>its presence in the scar plate?</b></p> <p>6 A. Well, it's bent by the mesh fiber,</p> <p>7 you can see clearly that it deviates from straight</p> <p>8 course.</p> <p>9 <b>Q. Anything about that that makes you</b></p> <p>10 <b>have an opinion that this is causing any symptoms</b></p> <p>11 <b>in the person who has this mesh?</b></p> <p>12 MR. ORENT: Objection. Form.</p> <p>13 THE WITNESS: Probably, the nerve is</p> <p>14 irritated by these fibers higher, because it is a</p> <p>15 direct compression on the nerve.</p> <p>16 BY MR. THOMAS:</p> <p>17 <b>Q. But there's nothing about this</b></p> <p>18 <b>slide, just like the other slides, which tells you</b></p> <p>19 <b>that the neurovascular bundle in Figure Set 10i,</b></p> <p>20 <b>actually caused symptoms in the person who had this</b></p> <p>21 <b>mesh?</b></p> <p>22 MR. ORENT: Objection.</p> <p>23 THE WITNESS: We discuss this before.</p> <p>24 The degree of symptoms, the expression by the</p> <p>25 patient is a complex process.</p>
<p style="text-align: right;">Page 223</p> <p>1 tissue growing inside and filled the two-block</p> <p>2 structure.</p> <p>3 <b>Q. And are you able to tell from this</b></p> <p>4 <b>image, whether it was curled on placement or curled</b></p> <p>5 <b>after placement?</b></p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: No.</p> <p>8 BY MR. THOMAS:</p> <p>9 <b>Q. Anything else remarkable about</b></p> <p>10 <b>Figure Set 10h?</b></p> <p>11 A. No. Curling, scar encapsulation,</p> <p>12 scar filling.</p> <p>13 <b>Q. Page 59, Figure Set 10i:</b></p> <p>14 <b>"Neurovascular bundle with rolled TVT tape, S100</b></p> <p>15 <b>stain. Additional TVT cases."</b></p> <p>16 <b>Is this from the same or a different</b></p> <p>17 <b>patient as set 10h?</b></p> <p>18 A. I don't remember now.</p> <p>19 <b>Q. Do you know if it's a TVT or</b></p> <p>20 <b>TVT-O?</b></p> <p>21 A. No.</p> <p>22 <b>Q. What are you trying to show in</b></p> <p>23 <b>Figure 10h?</b></p> <p>24 A. It's a single picture for single</p> <p>25 purpose as 10c, on page 52. A neurovascular bundle</p>	<p style="text-align: right;">Page 225</p> <p>1 So I can say that this is abnormal,</p> <p>2 this is a mechanism for symptoms, and then that can</p> <p>3 happen.</p> <p>4 BY MR. THOMAS:</p> <p>5 <b>Q. And the reason why you say it's</b></p> <p>6 <b>abnormal is because the mesh fiber causes this</b></p> <p>7 <b>bundle to alter its path?</b></p> <p>8 A. Yes.</p> <p>9 <b>Q. Anything else?</b></p> <p>10 A. No.</p> <p>11 <b>Q. Page 60.</b></p> <p>12 A. Yes.</p> <p>13 <b>Q. Figure Set 10j: "A rolled TVT</b></p> <p>14 <b>sling sectioned parallel and perpendicular to the</b></p> <p>15 <b>roll. Additional TVT cases."</b></p> <p>16 <b>Do you know whether this is a TVT or</b></p> <p>17 <b>TVT-O?</b></p> <p>18 MR. ORENT: Objection.</p> <p>19 THE WITNESS: No.</p> <p>20 BY MR. THOMAS:</p> <p>21 <b>Q. What is the significance of this</b></p> <p>22 <b>slide to show what you showed in previous slides.</b></p> <p>23 <b>That is, the fact of the curling?</b></p> <p>24 A. Fact of the curling and mechanism</p> <p>25 for erosion on page 61, I demonstrate how the</p>

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<p>1 erosion occurred. Because one end of this curled 2 tape became eroded. 3 <b>Q. Okay. So this is, the dark end of</b> 4 <b>the tape on page 60 and on 61, it is in fact an</b> 5 <b>erosion?</b> 6 A. Yes, it's -- 7 <b>Q. Where did it erode?</b> 8 A. In the mucosa, in vaginal mucosa. 9 <b>Q. Did it erode into another organ?</b> 10 A. No, it eroded through the mucosa 11 into the vagina. 12 <b>Q. Do you distinguish between an</b> 13 <b>erosion and an exposure?</b> 14 A. Technically, there is a 15 distinction. The terms are used interchangeably, 16 so there is no agreement which one is -- 17 <b>Q. Let's use the technical terms,</b> 18 <b>just so you and are communicating. Is this an</b> 19 <b>erosion or an exposure?</b> 20 A. Both. 21 <b>Q. Okay.</b> 22 A. Because the mucosa eroded on top 23 of it and mesh became exposed. 24 <b>Q. Okay. But in terms of the mesh</b> 25 <b>going into or eroding into another organ, that</b></p>	<p>1 <b>to see the extent to which this was a painful</b> 2 <b>experience for her?</b> 3 A. This is commonsense. This is a 4 chronic and open wound; would it hurt? Of course 5 it would. 6 <b>Q. Go to page 61. Figure Set 11b.</b> 7 <b>Is this the same mesh?</b> 8 A. No, it's a different one. 9 <b>Q. All right. Is this a TVT or a</b> 10 <b>TVT-O?</b> 11 A. I don't know. 12 <b>Q. And what are you trying to show in</b> 13 <b>Figure Set 11b?</b> 14 A. Similar mechanism for erosion, the 15 mesh somehow rotated, probably through curling of 16 the edges and then became exposed. The edge 17 pierced through the mucosa. 18 <b>Q. And this is an erosion, as you've</b> 19 <b>defined it, in the last section, some people may</b> 20 <b>call it an exposure, correct?</b> 21 A. Yes. It's called -- if you want 22 to call exposure, we will call it exposure. So the 23 mesh became exposed. 24 <b>Q. And what does the mesh in this</b> 25 <b>tissue sample tell you?</b></p>
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<p>1 <b>didn't happen here?</b> 2 A. Well, it eroded into the mucosa. 3 <b>Q. Okay. But just the mucosa, not</b> 4 <b>the bladder, not the rectum?</b> 5 A. Not the organs. Because it is a 6 different location. 7 <b>Q. All right. And do you remember</b> 8 <b>this patient?</b> 9 A. No. 10 <b>Q. Do you know how this patient was</b> 11 <b>treated?</b> 12 A. By sling excision. 13 <b>Q. Do you know how it worked out?</b> 14 <b>How she recovered from the excision?</b> 15 A. Better that she didn't have eroded 16 mesh anymore after surgery. Maybe it eroded again 17 in a different place. 18 <b>Q. Do you know whether she</b> 19 <b>experienced pain as a part of this?</b> 20 A. Most likely she did. 21 <b>Q. Do you know whether she</b> 22 <b>experienced pain as part of this?</b> 23 A. The degree of pain, as I said, I 24 don't remember now. But most likely she did. 25 <b>Q. You have not consulted her records</b></p>	<p>1 A. The position, see the position is 2 towards the mucosa. So it's not bilateral to the 3 mucosa, it's angled. And the edge, or the end of 4 the tape became exposed, pierced through the 5 mucosa. And the site of exposure became infected 6 and now there is acute inflammation surrounding. 7 <b>Q. How do you know that this mesh was</b> 8 <b>infected?</b> 9 A. Because there is acute 10 inflammation in there. 11 <b>Q. Do you know how long this woman</b> 12 <b>had this sling before it was removed?</b> 13 A. I don't remember. 14 <b>Q. Are you able to tell from this</b> 15 <b>slide whether this mesh was placed this way or</b> 16 <b>whether it changed after it was placed?</b> 17 A. It's hard to place it like this, 18 because you can see it's clearly perpendicular. So 19 I just cannot imagine it. 20 <b>Q. Do you know?</b> 21 MR. ORENT: Objection. 22 THE WITNESS: I don't know for sure, 23 but this would be a really difficult position to 24 achieve during placement. 25</p>

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<p>1 BY MR. THOMAS:</p> <p>2 <b>Q. Anything else remarkable about</b></p> <p>3 <b>your description of set 11b?</b></p> <p>4 A. No, we discussed most of it.</p> <p>5 <b>Q. Anything else you want to talk</b></p> <p>6 <b>about? You said "most".</b></p> <p>7 A. Sorry.</p> <p>8 <b>Q. Page 63, Figure Set 11c: "Exposed</b></p> <p>9 <b>edge of TVT sling rotated towards the mucosa.</b></p> <p>10 <b>Additional TVT cases".</b></p> <p>11 <b>Do you know whether this is a TVT or</b></p> <p>12 <b>TVT-O?</b></p> <p>13 A. No, I don't.</p> <p>14 <b>Q. And what is your purpose of</b></p> <p>15 <b>including Figure Set 11c?</b></p> <p>16 A. Just mechanism of exposure,</p> <p>17 because the edge is pointing towards mucosa.</p> <p>18 So it's a near exposed position in this</p> <p>19 case. Probably exposure occurred somewhere either</p> <p>20 more superficial, or deeper in the block.</p> <p>21 <b>Q. As you're looking at that mesh, is</b></p> <p>22 <b>the mesh -- you show the yellow portion of the mesh</b></p> <p>23 <b>going from the bottom of the figure to the top of</b></p> <p>24 <b>the figure. Is that the width of the mesh?</b></p> <p>25 A. With the length, it's very hard to</p>	<p>1 curls up like this.</p> <p>2 <b>Q. Is this a multiple revision?</b></p> <p>3 A. I don't know.</p> <p>4 <b>Q. You don't know?</b></p> <p>5 A. (Witness nods.)</p> <p>6 <b>Q. Okay. For the other mesh</b></p> <p>7 <b>erosions, or exposures that you've discussed on 58,</b></p> <p>8 <b>59, 60, 61, 62 and now 63, do you know whether</b></p> <p>9 <b>those are first revision cases, second revision</b></p> <p>10 <b>cases, or multiple revision cases?</b></p> <p>11 MR. ORENT: Objection.</p> <p>12 THE WITNESS: I don't remember exactly.</p> <p>13 Sometimes it's first revision, sometimes five, six</p> <p>14 revisions.</p> <p>15 BY MR. THOMAS:</p> <p>16 <b>Q. You just don't know?</b></p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: If I go through records,</p> <p>19 if it was individual report of a case, I go through</p> <p>20 records thoroughly, so I know exactly how many</p> <p>21 revisions it was.</p> <p>22 BY MR. THOMAS:</p> <p>23 <b>Q. Go to page 64. Figure Set 11b, is</b></p> <p>24 <b>that part of Figure Set 11c, or is that different?</b></p> <p>25 A. No, it's different.</p>
Page 231	Page 233
<p>1 determine in this place. So the mesh is either in</p> <p>2 this shape (indicating), or this shape</p> <p>3 (indicating).</p> <p>4 In any case, one of the edges is</p> <p>5 pointing towards mucosa.</p> <p>6 <b>Q. When you talk about -- strike</b></p> <p>7 <b>that. This mesh when placed, is going to stretch</b></p> <p>8 <b>from one side of the abdomen to the other, isn't</b></p> <p>9 <b>it?</b></p> <p>10 A. Yes. But we are talking about</p> <p>11 mucosa. So it is a very short stretch of the mesh</p> <p>12 right where it goes between the urethra and vaginal</p> <p>13 wall.</p> <p>14 <b>Q. I understand that. But my point</b></p> <p>15 <b>is, the only thing that can be exposed there is the</b></p> <p>16 <b>midpoint, not the ends, correct?</b></p> <p>17 A. Unless you cut one end, and then</p> <p>18 it becomes exposed again.</p> <p>19 <b>Q. Okay. And in order to cut the</b></p> <p>20 <b>end, you'd have to cut the end at the vaginal</b></p> <p>21 <b>mucosa, correct?</b></p> <p>22 A. Inside. So what happens -- first</p> <p>23 exposure occurs, it curls up like this. So this</p> <p>24 part is exposed, there is a revision surgery, one</p> <p>25 end is cut, the patient is left and sometimes it</p>	<p>1 <b>Q. How can you tell?</b></p> <p>2 A. It's a different slide.</p> <p>3 <b>Q. Okay. Is it a different patient?</b></p> <p>4 A. I don't remember.</p> <p>5 <b>Q. Okay.</b></p> <p>6 A. It may or may not be.</p> <p>7 <b>Q. Okay. Do you know if it's TVT or</b></p> <p>8 <b>TVT-O?</b></p> <p>9 A. No.</p> <p>10 <b>Q. Page 65, Figure Set 11e; isn't</b></p> <p>11 <b>that the same as Figure Set 11c?</b></p> <p>12 A. I just noticed, something</p> <p>13 happened.</p> <p>14 <b>Q. You liked that one?</b></p> <p>15 A. Could have been pasted twice or</p> <p>16 selected and pasted -- I don't remember. Something</p> <p>17 happened here. So I probably intended to insert</p> <p>18 different picture, but this one made it.</p> <p>19 <b>Q. Okay. I think we can say that</b></p> <p>20 <b>63 and 65 came from the same patient?</b></p> <p>21 A. Yes. It just shows you that I</p> <p>22 don't have an army of people helping me, I'm just</p> <p>23 alone.</p> <p>24 <b>Q. I understand. Let's go to</b></p> <p>25 <b>page 66, Figure Set 12.</b></p>

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<p style="text-align: right;">Page 234</p> <p>1 A. Yes.</p> <p>2 <b>Q. This is additional TVT cases. Do</b></p> <p>3 <b>you know whether this is a single mesh or multiple</b></p> <p>4 <b>meshes?</b></p> <p>5 A. What do you mean a single mesh --</p> <p>6 <b>Q. There are four frames here.</b></p> <p>7 <b>Excuse me, there are two frames here.</b></p> <p>8 <b>Do you know if it's the same one</b></p> <p>9 <b>patient or two?</b></p> <p>10 A. No.</p> <p>11 <b>Q. You don't know whether it's one or</b></p> <p>12 <b>two?</b></p> <p>13 A. No.</p> <p>14 <b>Q. Do you know whether it's TVT or</b></p> <p>15 <b>TVT-O?</b></p> <p>16 A. No.</p> <p>17 <b>Q. What are you trying to show in the</b></p> <p>18 <b>top image on page 66, Figure Set 12.</b></p> <p>19 A. Acute inflammation at the site of</p> <p>20 exposure.</p> <p>21 <b>Q. When you say acute inflammation,</b></p> <p>22 <b>is that different from infection?</b></p> <p>23 A. No. Acute inflammation is</p> <p>24 reaction to infection. Technically, it's the same</p> <p>25 pathological process.</p>	<p style="text-align: right;">Page 236</p> <p>1 <b>correct?</b></p> <p>2 A. You're correct.</p> <p>3 <b>Q. Thank you. And in the lower image</b></p> <p>4 <b>on Figure Set 12, the yellow represents</b></p> <p>5 <b>polypropylene?</b></p> <p>6 A. That is correct.</p> <p>7 <b>Q. And the presence of neutrophils</b></p> <p>8 <b>again shows the acute inflammation?</b></p> <p>9 A. That's correct.</p> <p>10 <b>Q. Anything else remarkable about</b></p> <p>11 <b>that slide?</b></p> <p>12 A. No.</p> <p>13 MR. THOMAS: I need to take a break,</p> <p>14 please.</p> <p>15 -- RECESS AT 3:19 --</p> <p>16 -- UPON RESUMING AT 3:23 --</p> <p>17 BY MR. THOMAS:</p> <p>18 <b>Q. Doctor, I understand from prior</b></p> <p>19 <b>depositions that when you analyzed your</b></p> <p>20 <b>medical-legal cases that you prepared your own, for</b></p> <p>21 <b>lack of a better description, your own pathology</b></p> <p>22 <b>report. I think you called it a synoptic recording</b></p> <p>23 <b>for each of the plaintiffs?</b></p> <p>24 A. Not for medical-legal. I do it</p> <p>25 for all mesh cases, it's a part of research.</p>
<p style="text-align: right;">Page 235</p> <p>1 <b>Q. I was just going to ask you that.</b></p> <p>2 <b>Can you diagnose infection from this slide?</b></p> <p>3 A. Yes, I can.</p> <p>4 <b>Q. And based on what?</b></p> <p>5 A. Based on the acute inflammation.</p> <p>6 <b>Q. Okay. And what is it about the</b></p> <p>7 <b>slide that shows the acute inflammation?</b></p> <p>8 A. The neutrophils.</p> <p>9 <b>Q. And the slide below that, again,</b></p> <p>10 <b>shows acute inflammation, and that may or may not</b></p> <p>11 <b>be the same patient?</b></p> <p>12 A. That's correct. I have feeling</p> <p>13 that they are different patients. I think one</p> <p>14 of -- the top one is the later case, the bottom one</p> <p>15 is an earlier case.</p> <p>16 <b>Q. As you sit here, do you know which</b></p> <p>17 <b>ones they are?</b></p> <p>18 A. The quality of the histology and</p> <p>19 the quality of the picture.</p> <p>20 <b>Q. In the top image, where you show</b></p> <p>21 <b>the acute inflammation, is there mesh in that</b></p> <p>22 <b>image?</b></p> <p>23 A. Underneath, if you go a little bit</p> <p>24 over.</p> <p>25 <b>Q. This doesn't appear in the image,</b></p>	<p style="text-align: right;">Page 237</p> <p>1 <b>Q. Do you have those kinds of</b></p> <p>2 <b>recordings for all of the patients that are in your</b></p> <p>3 <b>report?</b></p> <p>4 MR. ORENT: Objection.</p> <p>5 THE WITNESS: May or may not. Probably</p> <p>6 I don't have for all patients. Some cases are</p> <p>7 probably not even signed out, so the report is not</p> <p>8 completed yet.</p> <p>9 BY MR. THOMAS:</p> <p>10 <b>Q. I guess my point is that we didn't</b></p> <p>11 <b>get any of those on your thumb drive. And I'm</b></p> <p>12 <b>curious if there's some of those that we don't</b></p> <p>13 <b>have. We have a lot of them in the Huskey, Edwards</b></p> <p>14 <b>case or the Bellew case -- in the Bellew case, you</b></p> <p>15 <b>produced those to us for the --</b></p> <p>16 A. Yes. When I started doing my</p> <p>17 research, I realized that I needed more or less</p> <p>18 standardized approach when I examined the meshes.</p> <p>19 And I started entering them as a</p> <p>20 synoptic report, which is a specific pre-set number</p> <p>21 of parameters, so I don't forget and they're all</p> <p>22 analyzed in the same manner so they can compare</p> <p>23 them. It has nothing to do with medical-legal</p> <p>24 cases, or nothing else. It's pure documentation</p> <p>25 for research purposes.</p>

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<p style="text-align: right;">Page 238</p> <p>1 <b>Q. Do you have that for each of the</b>  2 <b>slides that are in this report?</b>  3 A. As I said --  4 MR. ORENT: Objection.  5 THE WITNESS: -- I don't have all of  6 these patients, some of the reports are not  7 finalized.  8 BY MR. THOMAS:  9 <b>Q. I'm going to ask you to produce</b>  10 <b>those that you do have.</b>  11 I have a --  12 A. If it's medical-legal case and  13 you're entitled to see the information.  14 <b>Q. Okay. I have a title of a study,</b>  15 <b>we talked before about your chemical oxidation</b>  16 <b>study you were performing, and I asked you about</b>  17 <b>the recipe for the chemicals to which you're</b>  18 <b>exposing the TVTs to.</b>  19 A. You mean hydrogen peroxide with  20 chromium salt catalyst?  21 <b>Q. Yes.</b>  22 A. Okay. I remember.  23 <b>Q. And there was a study we found</b>  24 <b>called, "Controlled Peroxide Degradation of</b>  25 <b>Polypropylene - Rheological Properties and</b></p>	<p style="text-align: right;">Page 240</p> <p>1 opinions, I would go back in my pool of images, for  2 TVT and TVT-O cases, and search for best images  3 representing that specific feature.  4 <b>Q. I see. So when you say "best</b>  5 <b>images", you went back through about 100 different</b>  6 <b>TVTs and TVT-Os did you say?</b>  7 A. No, I said slings.  8 <b>Q. I'm sorry. How many TVTs and</b>  9 <b>TVT-Os have you looked at?</b>  10 A. Ballpark of 30 to 40.  11 <b>Q. Okay. And so you went back</b>  12 <b>through your 30 to 40 to identify those that best</b>  13 <b>represented the features that you wanted to show?</b>  14 A. Images.  15 MR. ORENT: Objection.  16 BY MR. THOMAS:  17 <b>Q. Okay. Images?</b>  18 A. I didn't take new images of  19 various cases, I just used those images which were  20 taken already. The only new images that I produced  21 are the cases I received as a consulting trial set.  22 (Reporter sought clarification.)  23 A. Trial set, as a set to facilitate  24 at trial.  25 <b>Q. Let's go to Exhibit No. 2.</b></p>
<p style="text-align: right;">Page 239</p> <p>1 <b>Prediction of MWD From Rheological Data". Lead</b>  2 <b>author, Azizi, A-Z-I-Z-I. Including I. Ghasemi,</b>  3 <b>G-H-A-S-E-M-I, and M. KARRABI, K-A-R-R-A-B-I; does</b>  4 <b>that ring a bell?</b>  5 MR. ORENT: Objection.  6 THE WITNESS: You're asking the wrong  7 person, I'm really bad with names. I'm a  8 pathologist, I remember the slides but I don't  9 remember the names.  10 BY MR. THOMAS:  11 <b>Q. Do you have the study that you</b>  12 <b>used to come up with the recipe?</b>  13 A. Yes, I do. I can find it in my  14 hard drive, and I can find it.  15 <b>Q. Okay. Good.</b>  16 A. It's most likely at least in the  17 reference materials as well.  18 <b>Q. In the reference materials to your</b>  19 <b>report?</b>  20 A. Yes.  21 <b>Q. Okay. How did you determine which</b>  22 <b>of the slides from your total number of TVT-O and</b>  23 <b>TVT cases to include in the report?</b>  24 A. I went to features. So every time  25 I would be describing a specific feature in the</p>	<p style="text-align: right;">Page 241</p> <p>1 <b>Exhibit No. 2 is your supplemental</b>  2 <b>report served two days ago.</b>  3 A. Yes.  4 <b>Q. And when you received this, you</b>  5 <b>received slides from CAMC?</b>  6 A. Yes.  7 <b>Q. You didn't create your own slides?</b>  8 A. No, I did the staining.  9 (Reporter sought clarification.)  10 A. My lab did staining.  11 <b>Q. Do you know whether this is a TVT</b>  12 <b>or a TVT-O?</b>  13 A. No, I don't remember now.  14 <b>Q. Okay.</b>  15 A. I didn't review any medical  16 records for the consolidated trial cases.  17 <b>Q. And if you look at -- your pages</b>  18 <b>aren't numbered, but the first image, which is</b>  19 <b>identified as supplemental Figure EM1, it says:</b>  20 <b>"Portion of excised mucosa with underlying mesh,</b>  21 <b>H&amp;E magnification equivalent to 1.6X objective".</b>  22 <b>What is the significance of this image?</b>  23 A. It's just from my review showing  24 where the mesh is and how it relates to the mucosa.  25 <b>Q. Is there anything significant</b></p>

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<p style="text-align: right;">Page 242</p> <p>1 about this image in terms of risk factors or issues</p> <p>2 related to symptoms, clinical symptoms?</p> <p>3 A. Well, it's close. So it's an</p> <p>4 overview of the part which didn't get exposed but</p> <p>5 it shows the proximity. You know, that's</p> <p>6 significant.</p> <p>7 Q. And again, you don't know whether</p> <p>8 that was placed there or if it migrated there after</p> <p>9 placement, correct?</p> <p>10 MR. ORENT: Objection.</p> <p>11 THE WITNESS: That's correct.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Okay. Anything else remarkable</p> <p>14 about supplemental Figure EM1?</p> <p>15 A. No, there's scar tissue which</p> <p>16 encapsulates and fills the pore; that's about it.</p> <p>17 Q. Okay. Supplemental Figure EM2.</p> <p>18 Is this part of the same slide or is this a</p> <p>19 different slide?</p> <p>20 A. Oh, it's the same block.</p> <p>21 Q. Got it.</p> <p>22 A. Yeah, I think it's the same slide</p> <p>23 because I had only one H&amp;E slide.</p> <p>24 Q. It says in the first page you</p> <p>25 received unstained histological slides, plural.</p>	<p style="text-align: right;">Page 244</p> <p>1 showing supplemental Figure EM3?</p> <p>2 A. Again, shows mucosa and proximity</p> <p>3 of the mesh to mucosa. There is less than a half</p> <p>4 millimeter between the mesh and mucosa.</p> <p>5 Q. What is the distance between those</p> <p>6 two mesh fibers that are shown there?</p> <p>7 A. About a millimeter.</p> <p>8 Q. Okay. Supplemental Figure EM4,</p> <p>9 again, you're showing the foreign body inflammatory</p> <p>10 reaction?</p> <p>11 A. That's correct.</p> <p>12 Q. If you go to supplemental Figure</p> <p>13 EM5?</p> <p>14 A. Yes.</p> <p>15 Q. You indicate in the description,</p> <p>16 "acute inflammation and indication of mesh erosion</p> <p>17 and bacterial infection".</p> <p>18 Do you know whether this patient was</p> <p>19 diagnosed with an infection?</p> <p>20 A. No, I didn't read the records. I</p> <p>21 can see clearly there is bacterial infection</p> <p>22 triggering acute inflammation. If they saw it</p> <p>23 clinically or they didn't, I don't know. But even</p> <p>24 if they didn't, I would tell them there was an</p> <p>25 infection.</p>
<p style="text-align: right;">Page 243</p> <p>1 Did you only have one?</p> <p>2 A. For H&amp;E, I stain only one slide.</p> <p>3 So one slide was stained by H&amp;E method, one slide</p> <p>4 smooth muscle actin, and one slide S100 protein.</p> <p>5 Q. Okay. So supplemental Figure EM2</p> <p>6 is just more of a magnification of Figure EM1,</p> <p>7 correct?</p> <p>8 A. Yes, I think you can match it,</p> <p>9 it's from here.</p> <p>10 Q. And again, what you're trying to</p> <p>11 show is the foreign body reaction and inflammation?</p> <p>12 A. That is correct.</p> <p>13 Q. Where is the bark in this image?</p> <p>14 A. Which image? The EM2?</p> <p>15 Q. Yes.</p> <p>16 A. Maybe out of focus, maybe not</p> <p>17 there.</p> <p>18 Q. Okay. If you go to supplemental</p> <p>19 Figure EM3, this is another portion of the same</p> <p>20 image, correct?</p> <p>21 A. I think it's a different fragment,</p> <p>22 from the same slide but from a different piece of</p> <p>23 tissue. There were several pieces of tissue on the</p> <p>24 slide.</p> <p>25 Q. I see. And what is the purpose of</p>	<p style="text-align: right;">Page 245</p> <p>1 Q. Okay. Are you able to tell from</p> <p>2 these images that there was in fact a mesh erosion</p> <p>3 or mesh exposure?</p> <p>4 A. Yes.</p> <p>5 Q. And how can you tell that?</p> <p>6 A. There was a breakdown of mucosa</p> <p>7 and entry for infection. That's why I can see</p> <p>8 acute inflammation.</p> <p>9 Q. Where is the breakdown of the</p> <p>10 mucosa?</p> <p>11 A. I don't know. It didn't get in</p> <p>12 the section.</p> <p>13 Q. Are you assuming there's a</p> <p>14 breakdown of mucosa? You don't show one on the</p> <p>15 slide, correct?</p> <p>16 A. It's not an assumption. I can</p> <p>17 tell you with 100 percent certainty that there was</p> <p>18 a breakdown in the mucosa. Because if mucosa is</p> <p>19 not broken down, there is no bacterial insemination</p> <p>20 and acute inflammation.</p> <p>21 Q. Supplemental Figure EM6, you</p> <p>22 identify an obliterated artery?</p> <p>23 A. That is correct.</p> <p>24 Q. Anything remarkable about that</p> <p>25 finding beyond what we've talked about before, the</p>

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<p style="text-align: right;">Page 246</p> <p>1 <b>other obliterated artery?</b></p> <p>2 A. No. Exactly the same finding;</p> <p>3 interrupted blood supply.</p> <p>4 <b>Q. Which may or may not have clinical</b></p> <p>5 <b>significance?</b></p> <p>6 MR. ORENT: Objection.</p> <p>7 THE WITNESS: The degree of the changes</p> <p>8 may or may not be clinically apparent.</p> <p>9 BY MR. THOMAS:</p> <p>10 <b>Q. Okay. Because if the blood flow</b></p> <p>11 <b>is reduced or interrupted, they may receive blood</b></p> <p>12 <b>flow from other sources that would vascularize this</b></p> <p>13 <b>area?</b></p> <p>14 A. Yes. And then that was fibrosis,</p> <p>15 and then you mix up fibrosis which is caused by the</p> <p>16 mesh, then fibrosis lead to ischemia.</p> <p>17 It's a complex setting; how much of</p> <p>18 that would translate from one specific symptom</p> <p>19 would be difficult to discern.</p> <p>20 <b>Q. Obliteration of arteries is a risk</b></p> <p>21 <b>in any surgery of the pelvic floor, isn't it?</b></p> <p>22 MR. ORENT: Objection.</p> <p>23 THE WITNESS: Yes, there would be a</p> <p>24 risk for obliterated artery. But when you say</p> <p>25 obliterated artery in the tissue, which is not</p>	<p style="text-align: right;">Page 248</p> <p>1 <b>on the upper right-hand corner, how far is that</b></p> <p>2 <b>from the mesh?</b></p> <p>3 A. This one is --</p> <p>4 <b>Q. I'm talking about this one, upper</b></p> <p>5 <b>right?</b></p> <p>6 A. Oh, this one. See, with this one</p> <p>7 I don't even know. Maybe there is fiber right</p> <p>8 there, so it's pinching it.</p> <p>9 <b>Q. Do you know whether that's fiber</b></p> <p>10 <b>or not?</b></p> <p>11 A. That is hard to determine, I</p> <p>12 suspect there is, but I wasn't sure therefore I</p> <p>13 didn't put it.</p> <p>14 Now, looking at this image, I think</p> <p>15 there was a fiber. So that curvilinear shape is</p> <p>16 actually fiber compressing.</p> <p>17 <b>Q. How do you know that without</b></p> <p>18 <b>looking at it?</b></p> <p>19 A. Well, there's density, increased</p> <p>20 density. Similar to this area, the collagen is</p> <p>21 compacted right around the fibers.</p> <p>22 <b>Q. The tissue itself is pretty</b></p> <p>23 <b>irregular, isn't it?</b></p> <p>24 A. Well, see, this is clearly not the</p> <p>25 place where mesh fiber was. Because there is no</p>
<p style="text-align: right;">Page 247</p> <p>1 changed otherwise, because to obliterate an artery</p> <p>2 during surgery, you have to transect it.</p> <p>3 So by the time of mesh placement, this</p> <p>4 part would be separated. So this is an intact</p> <p>5 structure, which was not transected during surgery.</p> <p>6 It became obliterated later on.</p> <p>7 BY MR. THOMAS:</p> <p>8 <b>Q. If you go to supplemental -- how</b></p> <p>9 <b>can you tell that it happened after placement?</b></p> <p>10 A. It's not transected during</p> <p>11 surgery.</p> <p>12 <b>Q. I see.</b></p> <p>13 A. See how are the arteries being</p> <p>14 damaged --</p> <p>15 <b>Q. I understand.</b></p> <p>16 A. -- they get transected.</p> <p>17 <b>Q. I understand. Supplemental Figure</b></p> <p>18 <b>EM7a, "innervation of the scar tissue encapsulating</b></p> <p>19 <b>the mesh, S100". What are you showing in EM7a?</b></p> <p>20 A. Nerve branch. EM7a and 7b is the</p> <p>21 same image; 7b is labeled copy of 7a.</p> <p>22 <b>Q. Okay. And the arrows are pointing</b></p> <p>23 <b>to what?</b></p> <p>24 A. Nerve branches, or nerves.</p> <p>25 <b>Q. And for the nerve and nerve branch</b></p>	<p style="text-align: right;">Page 249</p> <p>1 capsule. If you look here, there is a capsule</p> <p>2 around the fiber, and if you look there, there is a</p> <p>3 capsule around the fiber. So I suspect there was a</p> <p>4 fiber here.</p> <p>5 <b>Q. Okay.</b></p> <p>6 A. Not here, but there.</p> <p>7 <b>Q. Looking at those nerves, is there</b></p> <p>8 <b>anything about the appearance of those nerves on</b></p> <p>9 <b>light microscopy that suggests to you they were</b></p> <p>10 <b>causing pain to the patient while the mesh was in</b></p> <p>11 <b>place?</b></p> <p>12 A. Could you repeat the question.</p> <p>13 I'm getting tired, sorry.</p> <p>14 MR. THOMAS: Would you repeat it for</p> <p>15 me, please?</p> <p>16 -- REPORTER'S NOTE: Question read back</p> <p>17 as recorded above.</p> <p>18 THE WITNESS: They're healthy nerves</p> <p>19 which can conduct pain. This is one of the main</p> <p>20 findings.</p> <p>21 BY MR. THOMAS:</p> <p>22 <b>Q. Okay. But again, there's nothing</b></p> <p>23 <b>about those that allow you to state that those</b></p> <p>24 <b>nerves were in fact reacting in a way to cause pain</b></p> <p>25 <b>in a patient while the mesh was implanted?</b></p>

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<p style="text-align: right;">Page 250</p> <p>1 A. The point of the picture is to</p> <p>2 show that that tissue is sensitive, so it can sense</p> <p>3 pain.</p> <p>4 Those nerve branches are not directly</p> <p>5 affected or at least one may, but the others are</p> <p>6 not directly affected by the mesh.</p> <p>7 The point is that tissue around it is</p> <p>8 innervated, so if you get a formation, if you get</p> <p>9 distortion, mechanical compression, then it can</p> <p>10 sense pain.</p> <p>11 <b>Q. Okay. Page 67 of your first</b></p> <p>12 <b>report, Figure Set 13a, you're talking about the</b></p> <p>13 <b>Prolene degradation layer.</b></p> <p>14 <b>Do you know if this is TVT or TVT-O?</b></p> <p>15 A. No.</p> <p>16 <b>Q. Do you know from what case this</b></p> <p>17 <b>comes?</b></p> <p>18 MR. ORENT: Objection.</p> <p>19 THE WITNESS: One of the consolidated</p> <p>20 cases.</p> <p>21 It's so similar to this study, which I</p> <p>22 think our scientists did in 87. I mean, even the</p> <p>23 arrow there is so similar.</p> <p>24 BY MR. THOMAS:</p> <p>25 <b>Q. So all of these images are from</b></p>	<p style="text-align: right;">Page 252</p> <p>1 A. Not image, slide.</p> <p>2 <b>Q. Slide, I'm sorry. Thank you.</b></p> <p>3 A. It came detached and displaced.</p> <p>4 <b>Q. Okay. And left what you have</b></p> <p>5 <b>described as the bark behind?</b></p> <p>6 A. Yes, that's correct.</p> <p>7 <b>Q. All right. Now, if you go to the</b></p> <p>8 <b>next page, page 73, again, additional TVT cases you</b></p> <p>9 <b>show an image where you show the polypropylene</b></p> <p>10 <b>still in place, correct?</b></p> <p>11 A. Yes. So now there is a</p> <p>12 separation. The core separated from the bark, but</p> <p>13 the core didn't detach completely and floated away.</p> <p>14 It's still close, but there was a split.</p> <p>15 <b>Q. And this is detached as a part of</b></p> <p>16 <b>the sample preparation process, correct?</b></p> <p>17 MR. ORENT: Objection.</p> <p>18 THE WITNESS: I don't know when it</p> <p>19 became detached. During surgery or during</p> <p>20 sectioning or during processing of the specimen.</p> <p>21 BY MR. THOMAS:</p> <p>22 <b>Q. Didn't happen in vivo, didn't</b></p> <p>23 <b>happen in the body?</b></p> <p>24 A. No. I suspect it doesn't happen</p> <p>25 that often. I very rarely see the bark actually in</p>
<p style="text-align: right;">Page 251</p> <p>1 <b>the consolidated cases through 72, and our experts</b></p> <p>2 <b>have these images, correct?</b></p> <p>3 A. Images -- they have slides.</p> <p>4 <b>Q. Slides, that's what I meant.</b></p> <p>5 A. Yes.</p> <p>6 <b>Q. I've talked to you, you've been</b></p> <p>7 <b>talked to at length about these images in prior</b></p> <p>8 <b>cases. Is there anything new and different about</b></p> <p>9 <b>what's expressed in these images that you haven't</b></p> <p>10 <b>seen before?</b></p> <p>11 A. It is exactly what I described in</p> <p>12 the published papers and previous reports. Exactly</p> <p>13 all, everything is the same.</p> <p>14 <b>Q. For the other cases that you begin</b></p> <p>15 <b>on 73, you had images from additional TVT cases.</b></p> <p>16 <b>Do you know whether those are TVT or TVT-O?</b></p> <p>17 A. No.</p> <p>18 MR. ORENT: Objection.</p> <p>19 BY MR. THOMAS:</p> <p>20 <b>Q. If you go to page 72, please?</b></p> <p>21 A. Yes.</p> <p>22 <b>Q. On page 72, you show an empty</b></p> <p>23 <b>space of detached core on the right image. And a</b></p> <p>24 <b>separated degradation bark. The empty space means</b></p> <p>25 <b>that the polypropylene dropped out of the image?</b></p>	<p style="text-align: right;">Page 253</p> <p>1 the tissue, being displaced in the tissue away from</p> <p>2 the fibers.</p> <p>3 <b>Q. Have you studied how mechanically</b></p> <p>4 <b>that happens?</b></p> <p>5 A. It just breaks off. There is a</p> <p>6 shear force, a breaking force.</p> <p>7 <b>Q. When you say a shear force, does</b></p> <p>8 <b>it shear off at the point where -- at about five</b></p> <p>9 <b>microns as the degradation ceases?</b></p> <p>10 A. It shears off in the interface</p> <p>11 between degraded and non-degraded.</p> <p>12 <b>Q. That's my point. Let's see if we</b></p> <p>13 <b>can agree with this. We're dealing with visual</b></p> <p>14 <b>observations here, correct?</b></p> <p>15 A. Yes, that's correct.</p> <p>16 <b>Q. And is it fair to understand with</b></p> <p>17 <b>respect to the images on page 73, where you show</b></p> <p>18 <b>detached core and degradation bark separated, are</b></p> <p>19 <b>you telling me that the detached core no longer has</b></p> <p>20 <b>a bark on it?</b></p> <p>21 A. They have a really thin layer of</p> <p>22 degraded material. Because the bark itself is not</p> <p>23 uniform. There is a higher degree of degradation</p> <p>24 on the outside and then smaller, smaller, smaller,</p> <p>25 smaller, smaller.</p>

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<p style="text-align: right;">Page 254</p> <p>1 <b>Q. Right.</b></p> <p>2 A. And then the degradation blends</p> <p>3 into not degraded polypropylene.</p> <p>4 <b>Q. Right.</b></p> <p>5 A. So at certain point these micro</p> <p>6 cracks, and mono cracks, they cannot go into this</p> <p>7 completely solid material, so it shears off</p> <p>8 somewhere there.</p> <p>9 I don't know if it's right at the end</p> <p>10 of them, close to them or how far they are. So</p> <p>11 there might be a layer of degraded polypropylene on</p> <p>12 the core. How thick it is, I wouldn't know.</p> <p>13 <b>Q. It's too small to measure by your</b></p> <p>14 <b>technique?</b></p> <p>15 A. That's correct.</p> <p>16 <b>Q. And your best estimate is that the</b></p> <p>17 <b>degradation bark that appears, as you've described</b></p> <p>18 <b>it in 73, is much as five microns?</b></p> <p>19 A. This is thinner. By looking at</p> <p>20 it, it is around two microns.</p> <p>21 <b>Q. Now what you show on page 75,</b></p> <p>22 <b>again from additional TVT cases, are the cracks</b></p> <p>23 <b>which you believe to be oxidized polypropylene,</b></p> <p>24 <b>correct?</b></p> <p>25 A. I don't believe -- I know.</p>	<p style="text-align: right;">Page 256</p> <p>1 A. And I figure I just leave it long</p> <p>2 enough, soon enough it will form and I will see</p> <p>3 which would -- in which fluid the bark is thicker.</p> <p>4 <b>Q. We talked before, I believe at</b></p> <p>5 <b>trial, about xylene and that you were conducting a</b></p> <p>6 <b>test to determine the extent to which xylene</b></p> <p>7 <b>impacted Prolene polypropylene; do you remember</b></p> <p>8 <b>that?</b></p> <p>9 A. Yes, I do.</p> <p>10 <b>Q. You told me, I believe, that you</b></p> <p>11 <b>were currently testing xylene to determine whether</b></p> <p>12 <b>xylene would impact Prolene polypropylene. Are you</b></p> <p>13 <b>still conducting that test?</b></p> <p>14 A. It's in the same set of jars. One</p> <p>15 of the jars contains xylene.</p> <p>16 <b>Q. Is that the only test that you're</b></p> <p>17 <b>doing with xylene?</b></p> <p>18 A. Well, previously I did testing for</p> <p>19 processing. So new mesh was put in regular xylene</p> <p>20 solution for time when it happens during tissue</p> <p>21 process.</p> <p>22 <b>Q. Did you produce that to me in the</b></p> <p>23 <b>jump drive Exhibit 4.</b></p> <p>24 A. No, these are the images of new</p> <p>25 pristine mesh. So this mesh had been through</p>
<p style="text-align: right;">Page 255</p> <p>1 <b>Q. Okay. And Figure Set 13i, do you</b></p> <p>2 <b>know if this is a TVT or TVT-O?</b></p> <p>3 A. No.</p> <p>4 <b>Q. Do you know how long this was in</b></p> <p>5 <b>the body?</b></p> <p>6 A. Certainly more than a year.</p> <p>7 <b>Q. Why do you say that?</b></p> <p>8 A. It's relatively thick. So if I</p> <p>9 check here where it's less tangential, this is the</p> <p>10 thickness, so it's definitely more than a year.</p> <p>11 <b>Q. When you devised your experiment</b></p> <p>12 <b>to intentionally oxidize polypropylene, did you</b></p> <p>13 <b>look at any methods that would allow you to</b></p> <p>14 <b>intentionally oxidize polypropylene in a time of</b></p> <p>15 <b>less than a year and a half?</b></p> <p>16 A. No, I didn't take them out.</p> <p>17 <b>Q. You misunderstood my question.</b></p> <p>18 <b>Did you attempt to identify any kind of</b></p> <p>19 <b>chemical recipe that would allow you to</b></p> <p>20 <b>intentionally oxidize Prolene more quickly than a</b></p> <p>21 <b>year and a half?</b></p> <p>22 A. No.</p> <p>23 <b>Q. Why not?</b></p> <p>24 A. I'm busy enough with other things.</p> <p>25 <b>Q. Okay.</b></p>	<p style="text-align: right;">Page 257</p> <p>1 xylene.</p> <p>2 <b>Q. Okay. Did you do any other</b></p> <p>3 <b>testing of pristine mesh impact on xylene over a</b></p> <p>4 <b>period of time?</b></p> <p>5 A. No. These only two. I did</p> <p>6 experiment for our routine processing, routine</p> <p>7 exposure to xylene, and then I started this</p> <p>8 experiment.</p> <p>9 I was testing it within month or two</p> <p>10 after it became exposed. I was thinking maybe it</p> <p>11 would get dissolved; it didn't. But the long-term</p> <p>12 effect will be studied later on together with other</p> <p>13 solutions.</p> <p>14 <b>Q. When you put the pristine mesh</b></p> <p>15 <b>through the sample preparation process, did you</b></p> <p>16 <b>perform any analytical chemistry on the mesh to</b></p> <p>17 <b>determine the extent to which xylene may have</b></p> <p>18 <b>altered the chemical structure of polypropylene?</b></p> <p>19 A. No.</p> <p>20 <b>Q. On page 84?</b></p> <p>21 A. Yes.</p> <p>22 <b>Q. Is page 84 another image of what</b></p> <p>23 <b>we had talked about at length on page 83?</b></p> <p>24 A. No, this is a different case.</p> <p>25 This is a case consolidated case. This is</p>

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<p style="text-align: right;">Page 258</p> <p>1 appearance of case from -- you can see the name of 2 the patient. 3 <b>Q. Okay. So this is -- strike that.</b> 4 <b>Did you do any analysis for bark on the</b> 5 <b>mesh depicted in Figure 16a?</b> 6 A. It's embedded in histology. It's 7 there. I mean -- 8 <b>Q. Have you ever done it?</b> 9 A. I didn't do anything specific. 10 It's embedded in histology. I can pull the slide 11 and take picture of the bark. 12 But again, this is a St. Michael's 13 patients, I'm not comfortable disclosing or giving 14 pictures specifically for trial or anything else. 15 I can tell you that I saw the bark. 16 <b>Q. So, Figure 16b on page 84 is</b> 17 <b>cracking on the surface of TVT mesh fibers. And</b> 18 <b>this is from the consolidated cases for patient</b> 19 <b>Dameron; is that correct?</b> 20 A. That is correct. 21 <b>Q. And these are the tissue samples</b> 22 <b>that you show on 84 that you had available to you?</b> 23 A. Yes. 24 <b>Q. And they had been stored in</b> 25 <b>formalin?</b></p>	<p style="text-align: right;">Page 260</p> <p>1 <b>Q. -- entitled, "Safety</b> 2 <b>Considerations for Synthetic Sling Surgery".</b> 3 <b>I know Dr. Blaivas. Who is Dr.</b> 4 <b>Purohit?</b> 5 A. I don't know. It's a team of 6 urologists and fellows working with Dr. Blaivas. 7 <b>Q. Okay. Did you consult with Dr.</b> 8 <b>Blaivas on the content of this article?</b> 9 A. Well, we wrote it together. 10 <b>Q. And that's my point. Did you work</b> 11 <b>with this whole team in writing the article?</b> 12 A. Yeah. We were changing, everybody 13 was contributing. It was changed several times, 14 redacted and... 15 <b>Q. Did you work with any individual</b> 16 <b>specifically, or did you write your own piece and</b> 17 <b>just look after your own section of the article?</b> 18 A. Oh, it's a joint effort. I mean, 19 the manuscript consult, everybody contributes, puts 20 one piece there, puts one piece there. 21 It's been changed and then editorial 22 office changes and then we change back and then so 23 forth. By the end of the day each single word may 24 be coming from a different person. 25 <b>Q. How many drafts did this Exhibit 5</b></p>
<p style="text-align: right;">Page 259</p> <p>1 A. No. We received it dry. Your 2 expert was there. 3 <b>Q. Okay.</b> 4 A. It was jar without formalin. 5 <b>Q. Do you know whether it was in</b> 6 <b>formalin?</b> 7 A. I don't. Probably it was at one 8 time, it leaked out but... that's my assumption. 9 <b>Q. You do know how long this was in</b> 10 <b>the body?</b> 11 A. No. 12 <b>Q. And obviously you don't know how</b> 13 <b>it was handled before it got to you, correct?</b> 14 A. No. 15 EXHIBIT NO. 5: Study Entitled "Safety 16 Considerations for Synthetic Sling 17 Surgery" in which Dr. Vladimir Iakovlev 18 appears as an author. 19 BY MR. THOMAS: 20 <b>Q. Doctor, I'm going to hand you</b> 21 <b>what's been marked as deposition Exhibit No. 5.</b> 22 A. Yes. 23 <b>Q. Deposition Exhibit No. 5 is a</b> 24 <b>review study in which you appear as an author --</b> 25 A. Yes.</p>	<p style="text-align: right;">Page 261</p> <p>1 <b>go through?</b> 2 A. Five, six. 3 <b>Q. Do you still have those drafts?</b> 4 MR. ORENT: Objection. 5 THE WITNESS: Yes, I do. But I mean 6 this is more of a delicate issue because there are 7 many authors involved and there is research 8 produced information, and it's a work in progress. 9 What became public is what we see right 10 in front of us. What we decided to be correct to 11 be exposed to the public. 12 BY MR. THOMAS: 13 <b>Q. Other than the journal itself, was</b> 14 <b>anybody else involved in the preparation of</b> 15 <b>Exhibit 5?</b> 16 A. What do you mean? 17 <b>Q. Did you have any contribution from</b> 18 <b>any other source other than the authors that were</b> 19 <b>listed in the preparation of the article?</b> 20 A. Everybody listed as authors, 21 everybody who contributed is here. Well, editorial 22 office was working with it also. 23 <b>Q. And who did you work with at the</b> 24 <b>editorial office?</b> 25 A. I don't remember now.</p>

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<p>1 <b>Q. Okay.</b></p> <p>2 A. I mean, they send their paper,</p> <p>3 they said, okay, this revision needs to be</p> <p>4 reviewed, please check this, please check that,</p> <p>5 they suggest some changes, mainly just style. Very</p> <p>6 strict regarding style.</p> <p>7 <b>Q. You said something earlier today,</b></p> <p>8 <b>I want to make sure I understand. In this</b></p> <p>9 <b>document, there is reference to work that you have</b></p> <p>10 <b>done on different meshes in the medical-legal</b></p> <p>11 <b>setting.</b></p> <p>12 <b>I thought I understood you to say that</b></p> <p>13 <b>you didn't use the slides that were provided to you</b></p> <p>14 <b>by Dr. Kreutzer, but that you cut new slides from</b></p> <p>15 <b>existing blocks and conducted your analysis on</b></p> <p>16 <b>those new slides; is that correct?</b></p> <p>17 A. For some cases, I received only</p> <p>18 slides, stained and unstained. For some cases I</p> <p>19 received blocks. As far as I remember, it's been</p> <p>20 long time.</p> <p>21 So I could either use unstained slides</p> <p>22 which came together with stained slides, or I could</p> <p>23 ask my lab to do recuts from the blocks which were</p> <p>24 made before me.</p> <p>25 <b>Q. All right. So, your best</b></p>	<p>1 <b>reporting longer-term complications, reports pain</b></p> <p>2 <b>greater than six weeks for either retropubic or</b></p> <p>3 <b>transobturator tape slings at 3.5 percent, correct?</b></p> <p>4 A. Which line?</p> <p>5 <b>Q. Third from the bottom, longer-term</b></p> <p>6 <b>complications. Do you see it, for refractory pain</b></p> <p>7 <b>greater than six weeks?</b></p> <p>8 A. So the incidence range is from 4.1</p> <p>9 to 30 percent.</p> <p>10 <b>Q. The complications percentage of</b></p> <p>11 <b>patients that report refractory pain greater than</b></p> <p>12 <b>six weeks is 3.5 percent, correct?</b></p> <p>13 A. What I see is 4.1 to 30 percent.</p> <p>14 <b>Q. Well --</b></p> <p>15 A. Third line from the bottom.</p> <p>16 <b>Q. I understand that's the mean and</b></p> <p>17 <b>the range, correct?</b></p> <p>18 A. Yes.</p> <p>19 <b>Q. 4.1?</b></p> <p>20 A. Sorry, 4.1 is mean. Yes, you're</p> <p>21 correct. I need my glasses.</p> <p>22 So this is -- the range is from 0 to</p> <p>23 30 percent.</p> <p>24 <b>Q. But the average -- excuse me --</b></p> <p>25 <b>the percentage of patients at 7,084 that report</b></p>
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<p>1 <b>recollection it was a mixture of previously</b></p> <p>2 <b>existing slides or recuts from this mesh that you</b></p> <p>3 <b>had obtained from Dr. Kreutzer, correct?</b></p> <p>4 A. Yes.</p> <p>5 <b>Q. Is the same thing true with your</b></p> <p>6 <b>other mesh specimens that were involved in</b></p> <p>7 <b>medical-legal field, that on some occasions you'd</b></p> <p>8 <b>use existing slides and some occasions you'd use</b></p> <p>9 <b>recuts or you'd have recuts made of existing</b></p> <p>10 <b>blocks?</b></p> <p>11 A. That's correct. Depends on</p> <p>12 situation.</p> <p>13 <b>Q. I assume you stand by all the</b></p> <p>14 <b>findings in this report, correct?</b></p> <p>15 A. It's not findings; this report is</p> <p>16 a review. So it's more based on the other papers.</p> <p>17 <b>Q. Okay?</b></p> <p>18 A. The only thing which was produced</p> <p>19 in this paper from us personally was figures.</p> <p>20 <b>Q. Let's go to one of those figures</b></p> <p>21 <b>on page 4.</b></p> <p>22 A. You mean the table?</p> <p>23 <b>Q. Table two on page 4?</b></p> <p>24 A. Yes.</p> <p>25 <b>Q. And this review paper, in</b></p>	<p>1 <b>pain greater than six weeks, is 247 or 3.5 percent,</b></p> <p>2 <b>correct? Is that right?</b></p> <p>3 A. Yes and no. So this is a review</p> <p>4 of previously published studies. So the quality of</p> <p>5 the studies is different, methodology is different.</p> <p>6 But when you check them, the pain over six weeks is</p> <p>7 reporting anywhere from 0 to 30 percent.</p> <p>8 <b>Q. Okay.</b></p> <p>9 A. With a mean, or average</p> <p>10 4.1 percent.</p> <p>11 <b>Q. But these numbers are correct,</b></p> <p>12 <b>aren't they?</b></p> <p>13 A. Well, from what we extracted at</p> <p>14 that stage from the papers, that's what we have.</p> <p>15 <b>Q. Okay. You went out and tried to</b></p> <p>16 <b>obtain complication rates for retropubic or TOT</b></p> <p>17 <b>slings, didn't you?</b></p> <p>18 A. Yes. The whole paper is just for</p> <p>19 slings.</p> <p>20 <b>Q. And as a part of looking at</b></p> <p>21 <b>long-term pain which is greater than six weeks, you</b></p> <p>22 <b>looked at 7,084 patients, correct?</b></p> <p>23 A. No, we didn't. The papers in</p> <p>24 combination.</p> <p>25 <b>Q. I understand. But you gathered</b></p>

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<p>1 <b>papers that looked at over 7,000 patients?</b></p> <p>2 MR. ORENT: Objection.</p> <p>3 THE WITNESS: That's what it says</p> <p>4 there, yes.</p> <p>5 BY MR. THOMAS:</p> <p>6 <b>Q. And in gathering the papers, who</b></p> <p>7 <b>was in charge of picking which studies you looked</b></p> <p>8 <b>at?</b></p> <p>9 A. That part -- it's not a study; it</p> <p>10 is a review.</p> <p>11 <b>Q. I apologize.</b></p> <p>12 A. That part of the review was done</p> <p>13 mainly by urologist.</p> <p>14 <b>Q. Do you know who that was?</b></p> <p>15 A. It's a team working with Dr.</p> <p>16 Blaivas.</p> <p>17 <b>Q. So the urologist, the clinicians,</b></p> <p>18 <b>are the people who are responsible for identifying</b></p> <p>19 <b>the studies to identify the complication rates?</b></p> <p>20 A. That's correct.</p> <p>21 <b>Q. And through their best efforts,</b></p> <p>22 <b>they identified a percentage of patients that have</b></p> <p>23 <b>pain more than six weeks at 3.5 percent, correct?</b></p> <p>24 A. That was an estimate of a minimal,</p> <p>25 a minimum number. So this is the bottom line. So</p>	<p>1 <b>complications looked to see how many people had</b></p> <p>2 <b>their pain resolved by surgery or some other</b></p> <p>3 <b>treatment?</b></p> <p>4 A. Those papers are reviews. Most of</p> <p>5 them didn't provide that information. They just</p> <p>6 provided numbers for complications.</p> <p>7 <b>Q. Did you do a literature search</b></p> <p>8 <b>yourself to determine the extent to which long-term</b></p> <p>9 <b>complications of chronic pain were resolved by</b></p> <p>10 <b>surgery or other treatment?</b></p> <p>11 A. Not to answer that specific</p> <p>12 question. Again, I mean, I only can read what is</p> <p>13 published. Because studies don't concentrate,</p> <p>14 don't focus on this question; I cannot get an</p> <p>15 answer.</p> <p>16 <b>Q. Well, this was your group's best</b></p> <p>17 <b>effort at presenting, in a reviewed paper, the rate</b></p> <p>18 <b>of complications for long-term pain, correct?</b></p> <p>19 MR. ORENT: Objection.</p> <p>20 THE WITNESS: Yes, you're correct.</p> <p>21 BY MR. THOMAS:</p> <p>22 <b>Q. Thank you.</b></p> <p>23 A. But the question is that if I made</p> <p>24 an effort to look for something which is barely</p> <p>25 ever published; that's why I answered that it's</p>
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<p>1 it's minimum of 3.5 percent of the patients will</p> <p>2 develop chronic pain.</p> <p>3 <b>Q. Okay.</b></p> <p>4 A. Which is -- probably doesn't say</p> <p>5 right away, but that was the minimum. It wasn't</p> <p>6 that we were implying that it's a true number.</p> <p>7 <b>Q. Do you know how many, for how many</b></p> <p>8 <b>of those 3.5 percent that the pain was ultimately</b></p> <p>9 <b>resolved?</b></p> <p>10 A. Again, 3.5 percent was minimum</p> <p>11 number.</p> <p>12 <b>Q. I understand. But for some of</b></p> <p>13 <b>those people they were cured of the chronic pain,</b></p> <p>14 <b>weren't they?</b></p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: After mesh removal?</p> <p>17 BY MR. THOMAS:</p> <p>18 <b>Q. Or for whatever treatment?</b></p> <p>19 MR. ORENT: Objection.</p> <p>20 BY MR. THOMAS:</p> <p>21 <b>Q. Do you know that?</b></p> <p>22 A. No, I don't know. I don't think</p> <p>23 it was in the published literature.</p> <p>24 <b>Q. That's fine. Do you know whether</b></p> <p>25 <b>the urologist group who were looking at the mesh</b></p>	<p>1 specifically to that question, would be difficult</p> <p>2 to do.</p> <p>3 -- RECESS AT 4:08 --</p> <p>4 -- UPON RESUMING AT 4:15 --</p> <p>5 BY MR. THOMAS:</p> <p>6 <b>Q. Doctor, let's go back to Exhibit</b></p> <p>7 <b>No. 5, page 5. I asked you about the wrong chart.</b></p> <p>8 <b>I asked you about the chart on page 4.</b></p> <p>9 <b>The chart on page 4 does retropubic and</b></p> <p>10 <b>obturator slings. The one on page 5 is limited to</b></p> <p>11 <b>retropubic slings; do you see at the top?</b></p> <p>12 A. Yes.</p> <p>13 <b>Q. And retropubic slings are what TVT</b></p> <p>14 <b>slings are, correct?</b></p> <p>15 A. Yes.</p> <p>16 <b>Q. And the long-term refractory pain</b></p> <p>17 <b>greater than six weeks reported by your group is</b></p> <p>18 <b>1.8 percent, correct?</b></p> <p>19 A. Yes, but it's not reported by our</p> <p>20 group.</p> <p>21 <b>Q. Collected by your group?</b></p> <p>22 A. Collected from other papers by our</p> <p>23 group, yes.</p> <p>24 <b>Q. And as a part of that, the group</b></p> <p>25 <b>looked at studies reporting on about 2,328</b></p>

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<p style="text-align: right;">Page 270</p> <p>1 patients, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. For the slide on page 82,</p> <p>4 about the -- 83, I'm sorry. About the image of the</p> <p>5 TVT mesh fibers immediately after surgery removal?</p> <p>6 A. Yes.</p> <p>7 Q. Did you submit any histology to</p> <p>8 the journal for publication?</p> <p>9 A. For this case?</p> <p>10 Q. For the journal. For --</p> <p>11 A. Which one?</p> <p>12 Q. In one of the studies you have the</p> <p>13 image of that --</p> <p>14 A. It's --</p> <p>15 Q. Is it the other journal?</p> <p>16 A. Yes, this one.</p> <p>17 Q. I'll come back to that.</p> <p>18 A. You mean histology of that</p> <p>19 specific case?</p> <p>20 Q. Yes.</p> <p>21 A. No.</p> <p>22 Q. Have you shared the histology of</p> <p>23 that specific slide with anybody period?</p> <p>24 MR. ORENT: Objection.</p> <p>25 THE WITNESS: No.</p>	<p style="text-align: right;">Page 272</p> <p>1 and Dr. Bendavid on this?</p> <p>2 A. Yes.</p> <p>3 Q. Did you receive any funding for</p> <p>4 your work in Exhibit 6?</p> <p>5 A. No.</p> <p>6 Q. Did Dr. Guelcher or Dr. Bendavid</p> <p>7 receive any funding for their work on Exhibit 6?</p> <p>8 A. No. The work actually was done</p> <p>9 mainly by me. Dr. Guelcher and Dr. Bendavid just</p> <p>10 contributed to the drafting of the manuscript.</p> <p>11 Q. What did Dr. Guelcher contribute</p> <p>12 to the manuscript?</p> <p>13 A. The drafting of the manuscript, we</p> <p>14 discussed mechanism of degradation, mechanically</p> <p>15 how it happens, oxidation and other aspects.</p> <p>16 Q. Do you view Dr. Guelcher as</p> <p>17 authoritative on the issue of oxidative</p> <p>18 degeneration -- excuse me.</p> <p>19 Do you view Dr. Guelcher as</p> <p>20 authoritative in the area of oxidative degradation</p> <p>21 of polypropylene?</p> <p>22 A. He's a bio engineer. He works in</p> <p>23 the area.</p> <p>24 Q. How do you feel about him? Do you</p> <p>25 view him as authoritative in the field?</p>
<p style="text-align: right;">Page 271</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. So you're the only one that's ever</p> <p>3 looked at it?</p> <p>4 A. Pardon?</p> <p>5 Q. You're the only one that's ever</p> <p>6 looked at it?</p> <p>7 A. Yes. I don't think I have</p> <p>8 pictures, I didn't take pictures.</p> <p>9 Q. Okay. Why not?</p> <p>10 A. What for?</p> <p>11 Q. Okay.</p> <p>12 EXHIBIT NO. 6: Article entitled,</p> <p>13 "Degradation of Polypropylene in Vivo:</p> <p>14 A Microscopic Analysis of Mesh</p> <p>15 Explanted from Patients."</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Let me show you what's been marked</p> <p>18 as deposition Exhibit No. 6.</p> <p>19 Deposition Exhibit No. 6 is an article</p> <p>20 entitled, "Degradation of Polypropylene in Vivo: A</p> <p>21 Microscopic Analysis of Mesh Explanted from</p> <p>22 Patients". That was just recently released,</p> <p>23 correct?</p> <p>24 A. That is correct.</p> <p>25 Q. And you worked with Dr. Guelcher</p>	<p style="text-align: right;">Page 273</p> <p>1 MR. ORENT: Objection.</p> <p>2 THE WITNESS: I'm not sure if I can</p> <p>3 answer that question.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Okay?</p> <p>6 A. He's a specialist who works in the</p> <p>7 area and works in the field.</p> <p>8 Q. At any time, have you relied upon</p> <p>9 Dr. Guelcher to tell you, chemically, how</p> <p>10 polypropylene oxidizes?</p> <p>11 A. No. In fact, it wasn't my purpose</p> <p>12 to answer the question how it oxidizes. It only</p> <p>13 describes that it does oxidize.</p> <p>14 Q. So what role did Dr. Guelcher play</p> <p>15 in the preparation of Exhibit 6?</p> <p>16 A. Drafting of the manuscript, mainly</p> <p>17 the discussion part. He also suggested at one</p> <p>18 point when we started working on this, doing a</p> <p>19 myeloperoxidase stain. Again, in relation to</p> <p>20 oxidative degradation.</p> <p>21 Q. What role did Dr. Bendavid have in</p> <p>22 this study?</p> <p>23 A. Well, he actually brought me to</p> <p>24 this mesh field and he supplied, or some samples</p> <p>25 came from Shouldice Hospital, where he worked. And</p>

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<p style="text-align: right;">Page 274</p> <p>1 he also helped drafting the manuscript.</p> <p>2 <b>Q. In terms of the data gathering and</b></p> <p>3 <b>the conclusions contained herein, is this basically</b></p> <p>4 <b>your work?</b></p> <p>5 A. For the most part.</p> <p>6 <b>Q. And I hate to ask you again, but</b></p> <p>7 <b>what data gathering or conclusions did Dr. Guelcher</b></p> <p>8 <b>or Dr. Bendavid provide?</b></p> <p>9 A. Dr. Guelcher didn't gather any</p> <p>10 data. As you can read the manuscript or paper,</p> <p>11 it's all histology.</p> <p>12 <b>Q. Okay?</b></p> <p>13 A. So I've been collecting data and</p> <p>14 analyzing the samples.</p> <p>15 But Dr. Bendavid contributed with idea</p> <p>16 of degradation and contributing some samples,</p> <p>17 hernia samples, and Dr. Guelcher contributed in</p> <p>18 drafting the manuscript and also suggesting</p> <p>19 myeloperoxidase stain and suggesting what is the</p> <p>20 mechanism of degradation.</p> <p>21 But the histology itself, data</p> <p>22 collection and analysis, was done by me.</p> <p>23 <b>Q. As part of the preparation of this</b></p> <p>24 <b>paper, did you and your coauthors discuss</b></p> <p>25 <b>intentionally oxidizing polypropylene to see if it</b></p>	<p style="text-align: right;">Page 276</p> <p>1 what he's using, or I don't remember exactly how</p> <p>2 the conversation started, and he said that he's</p> <p>3 using recipe from that specific paper.</p> <p>4 <b>Q. I see.</b></p> <p>5 A. And I used it. We didn't have</p> <p>6 exchange of the samples, or testing of each other's</p> <p>7 samples.</p> <p>8 <b>Q. So you have never analyzed the</b></p> <p>9 <b>samples that he tested?</b></p> <p>10 A. No, never seen those.</p> <p>11 <b>Q. And you know that he's exposed</b></p> <p>12 <b>samples to five and six weeks' worth of exposure?</b></p> <p>13 A. I do know that.</p> <p>14 <b>Q. Okay.</b></p> <p>15 A. I do know that.</p> <p>16 <b>Q. Have you requested to look at</b></p> <p>17 <b>those or test those or analyze those in any form?</b></p> <p>18 A. There was a discussion. I don't</p> <p>19 know if I said that I don't want to do it because I</p> <p>20 have my own and I believe it needs to be a year.</p> <p>21 Or maybe they used all their samples</p> <p>22 for SEM, and they didn't have anything left. But</p> <p>23 at that time the decision was to wait for my</p> <p>24 samples to become mature.</p> <p>25 <b>Q. Okay. Did you submit this article</b></p>
<p style="text-align: right;">Page 275</p> <p>1 <b>would hold stain?</b></p> <p>2 A. No. This paper was started, or</p> <p>3 most of the data was collected even before I</p> <p>4 learned about this simulation model. So it wasn't</p> <p>5 a part.</p> <p>6 <b>Q. Did you ever discuss with Dr.</b></p> <p>7 <b>Guelcher different ways to intentionally oxidize</b></p> <p>8 <b>polypropylene?</b></p> <p>9 A. Later on. I mean, the manuscript</p> <p>10 was mainly written already and then we started</p> <p>11 discussing plans for the future. And then that's</p> <p>12 how I used the paper he suggested as a recipe for</p> <p>13 simulation.</p> <p>14 <b>Q. Okay. So Dr. Guelcher suggested</b></p> <p>15 <b>to you the paper that you used for the simulation?</b></p> <p>16 A. I think so.</p> <p>17 <b>Q. Okay?</b></p> <p>18 A. Maybe I saw it before, but he</p> <p>19 pointed that, that's the recipe he was using as</p> <p>20 well.</p> <p>21 <b>Q. Got it. Is Dr. Guelcher involved</b></p> <p>22 <b>in your experimental work on the samples that</b></p> <p>23 <b>you're now storing?</b></p> <p>24 A. No. I mean, I had my own samples.</p> <p>25 His contribution to this work is that I ask him</p>	<p style="text-align: right;">Page 277</p> <p>1 <b>to multiple journals?</b></p> <p>2 A. There was submission to at least</p> <p>3 two journals and the answer was really quick, next</p> <p>4 day. They said no, it's not in our scope. And I</p> <p>5 was aiming at really high impact like Nature, so...</p> <p>6 <b>Q. Nature turned it down?</b></p> <p>7 A. (Witness nods).</p> <p>8 <b>Q. Okay.</b></p> <p>9 A. Are you surprised?</p> <p>10 <b>Q. And so is the Journal of</b></p> <p>11 <b>Biomedical Materials the only other journal that</b></p> <p>12 <b>reviewed it?</b></p> <p>13 MR. ORENT: Objection.</p> <p>14 THE WITNESS: Yeah, this is my usual</p> <p>15 approach. For all my papers I start really high</p> <p>16 impact journal, hope for the best, and then go</p> <p>17 from there.</p> <p>18 BY MR. THOMAS:</p> <p>19 <b>Q. Now, was there a peer-review</b></p> <p>20 <b>process of this article?</b></p> <p>21 A. Yes. They ask for revisions, I</p> <p>22 did revisions, then we drafted it.</p> <p>23 <b>Q. How many drafts did you have of</b></p> <p>24 <b>Exhibit 6?</b></p> <p>25 A. We had one revision, one large</p>

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<p style="text-align: right;">Page 278</p> <p>1 revision. Part of the manuscript removed tables.  2 MR. ORENT: I object to this whole line  3 of questioning. It's outside of the scope of the  4 expert testimony, and moreover I think there's a  5 public policy interest in maintaining the integrity  6 of the editorial board process of the journals.  7 BY MR. THOMAS:  8 <b>Q. Do you still have your first</b>  9 <b>draft?</b>  10 MR. ORENT: Objection.  11 THE WITNESS: I can't answer that.  12 BY MR. THOMAS:  13 <b>Q. You can't?</b>  14 A. (Nods).  15 <b>Q. Why?</b>  16 A. It goes to the issues Mr. Orent  17 just mentioned.  18 <b>Q. Okay. So have you maintained a</b>  19 <b>file on the preparation, the data you gathered, the</b>  20 <b>submission process and the peer-review process for</b>  21 <b>Exhibit 6?</b>  22 A. Did I?  23 <b>Q. Yes.</b>  24 MR. ORENT: Objection.  25 THE WITNESS: Yes, I did.</p>	<p style="text-align: right;">Page 280</p> <p>1 <b>them are machine cut or laser cut?</b>  2 A. No.  3 <b>Q. You have four Prolift products; do</b>  4 <b>you see that?</b>  5 A. Yes, I do.  6 <b>Q. And then a number of hernia mesh</b>  7 <b>cases, correct?</b>  8 A. That is correct.  9 <b>Q. Of the 69 slings that you</b>  10 <b>analyzed, how many were medical-legal cases?</b>  11 A. The breakdown was about  12 70 percent. I cannot tell you exact number. But  13 roughly, it's for the whole set was 70 percent  14 medical-legal and 30 percent hospital cases.  15 And not necessarily St. Michael's.  16 They were coming from different hospitals.  17 <b>Q. Okay. Is it fair to say if</b>  18 <b>they're undetermined that they're not medical-legal</b>  19 <b>cases?</b>  20 A. At least 70 percent were  21 medical-legal.  22 <b>Q. I understand that, but I'm trying</b>  23 <b>to break it down further to find out which ones</b>  24 <b>were medical-legal and which ones were not.</b>  25 <b>And you have 45 hernia cases that you</b></p>
<p style="text-align: right;">Page 279</p> <p>1 BY MR. THOMAS:  2 <b>Q. I just ask you to maintain that</b>  3 <b>file and either I'll get it or I won't. Just don't</b>  4 <b>do anything to it; that's all I ask.</b>  5 <b>Just so I can short cut this. Is it</b>  6 <b>fair to say you're not going to answer any more</b>  7 <b>questions about the generation, drafting, peer</b>  8 <b>review, submission and publication of the article?</b>  9 A. It was a standard process. There  10 was nothing unusual about it.  11 <b>Q. But in terms of the details of it</b>  12 <b>you're not going to answer any questions about</b>  13 <b>that?</b>  14 A. No. I can tell that you there was  15 nothing unusual.  16 <b>Q. I understand. If you'll turn to</b>  17 <b>page 2, Table 1 is the sample and patient data?</b>  18 A. Yes.  19 <b>Q. And under "Slings", it says that</b>  20 <b>you have 28 TVT or TVT-Os; do you see that?</b>  21 A. That is correct.  22 <b>Q. Do you know the breakdown between</b>  23 <b>TVT and TVT-O?</b>  24 A. No.  25 <b>Q. Okay. Do you know whether any of</b></p>	<p style="text-align: right;">Page 281</p> <p>1 <b>identify as undetermined. I'm making an assumption</b>  2 <b>that because they're undetermined hernia cases that</b>  3 <b>they're probably not medical-legal cases; is that a</b>  4 <b>fair assumption?</b>  5 A. Some of them are medical-legal.  6 <b>Q. What percentage of the</b>  7 <b>undetermined hernia cases were medical-legal; do</b>  8 <b>you know?</b>  9 A. The undetermined are probably all  10 non-medical-legal. I don't think medical-legal is  11 undetermined.  12 <b>Q. That was my point?</b>  13 A. Yes.  14 <b>Q. So when we're making the</b>  15 <b>calculation of the 70 percent, is it safe for us to</b>  16 <b>exclude -- or strike that.</b>  17 <b>Is it safe for us to include the 45</b>  18 <b>undetermined hernia cases in the 30 percent of the</b>  19 <b>non-medical-legal cases?</b>  20 A. Yes, we can do that right away.  21 Those would be non-medical-legal cases.  22 <b>Q. Okay.</b>  23 A. There could be some potentially  24 medical-legal cases when I receive a specimen but I  25 have not received a history. They say, hold on to</p>

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<p style="text-align: right;">Page 282</p> <p>1 this -- may be medical-legal case later on.</p> <p>2 <b>Q. Okay?</b></p> <p>3 A. So it's not hard number.</p> <p>4 <b>Q. Right.</b></p> <p>5 A. But it's a ballpark.</p> <p>6 <b>Q. For the Ethicon TVT, TVT-O of</b></p> <p>7 <b>those 28 how many of them are medical-legal?</b></p> <p>8 A. At least 80 percent.</p> <p>9 <b>Q. Perhaps more?</b></p> <p>10 A. Possibly more.</p> <p>11 <b>Q. And included within the 28 Ethicon</b></p> <p>12 <b>TVT and TVT-O are the cases that you received from</b></p> <p>13 <b>Dr. Kreutzer, correct?</b></p> <p>14 A. Yes. Most of St. Michael's cases,</p> <p>15 when I had a record, were actually TVT. So I don't</p> <p>16 know for whatever reason most of those excised at</p> <p>17 St. Michael's were TVT.</p> <p>18 <b>Q. Okay. And in addition, you had</b></p> <p>19 <b>new TVT and TVT-O cases since Dr. Kreutzer, and</b></p> <p>20 <b>those would be included in this article as well?</b></p> <p>21 A. Yes.</p> <p>22 <b>Q. So, for example, the Edwards case</b></p> <p>23 <b>would probably be in this?</b></p> <p>24 A. Yes, it would be in there. I</p> <p>25 received the Edwards case before I received</p>	<p style="text-align: right;">Page 284</p> <p>1 <b>Q. Is it on the thumb drive?</b></p> <p>2 A. It's on the thumb drive. And you</p> <p>3 saw it before at various depositions.</p> <p>4 <b>Q. Thank you. I don't want to redo</b></p> <p>5 <b>that.</b></p> <p>6 <b>And when you do the eyepiece micrometer</b></p> <p>7 <b>and you measure, to what level can you measure?</b></p> <p>8 A. Initially, I had one micrometer.</p> <p>9 It was graded only to one micrometer. Now, I have</p> <p>10 little bit better so I can measure up to half a</p> <p>11 micrometer.</p> <p>12 <b>Q. When you were doing this study,</b></p> <p>13 <b>were you measuring at one micrometer?</b></p> <p>14 A. I was rounding to one micrometer;</p> <p>15 it was an older eyepiece.</p> <p>16 <b>Q. So the data in the study, you're</b></p> <p>17 <b>rounding your findings to the closest micrometer?</b></p> <p>18 A. Yes. To the full number.</p> <p>19 <b>Q. Did you round up always?</b></p> <p>20 MR. ORENT: Objection.</p> <p>21 THE WITNESS: No, it depends. If it's</p> <p>22 less than a half of the next gradation, it would go</p> <p>23 to the lower, but that's the usual rule for --</p> <p>24 BY MR. THOMAS:</p> <p>25 <b>Q. Okay, that's fine. And then when</b></p>
<p style="text-align: right;">Page 283</p> <p>1 specimen from Dr. Kreutzer.</p> <p>2 <b>Q. Okay. Interesting.</b></p> <p>3 <b>On page 3 of this study, you talk about</b></p> <p>4 <b>measuring the degradation layer's thickness?</b></p> <p>5 A. Yes.</p> <p>6 <b>Q. And you say a set of 23</b></p> <p>7 <b>mid-urethral slings was the largest uniform group</b></p> <p>8 <b>that fulfilled your criteria. Is that the slings</b></p> <p>9 <b>that you got from Dr. Kreutzer?</b></p> <p>10 A. Most of them came in that set of</p> <p>11 samples.</p> <p>12 <b>Q. All right. Tell me how you</b></p> <p>13 <b>physically measure the thickness of the stained</b></p> <p>14 <b>layer with the eyepiece micrometer?</b></p> <p>15 A. I would find fibers which are cut</p> <p>16 as perpendicular as possible and measure bark</p> <p>17 thickness on at least two occasions.</p> <p>18 And then measure -- I try to find</p> <p>19 another fiber, measure again, and then take median</p> <p>20 number, the most frequent I'm getting.</p> <p>21 <b>Q. Do you have the data that you</b></p> <p>22 <b>collected on those measurements?</b></p> <p>23 A. Yes, I do.</p> <p>24 <b>Q. Okay.</b></p> <p>25 A. I mean, you have it on the --</p>	<p style="text-align: right;">Page 285</p> <p>1 <b>you had two together -- so you had a total of four</b></p> <p>2 <b>measurements?</b></p> <p>3 A. I would aim at four measurements</p> <p>4 at least.</p> <p>5 <b>Q. And each one of those would go</b></p> <p>6 <b>through some rounding process?</b></p> <p>7 A. Yeah, I mean, the accuracy of</p> <p>8 measurement was within half a micrometer plus or</p> <p>9 minus.</p> <p>10 <b>Q. Okay. Now --</b></p> <p>11 A. But it would be random, up and</p> <p>12 down, up and down, so they would constantly change.</p> <p>13 <b>Q. Now, in some places in images we</b></p> <p>14 <b>looked at today, we didn't find any bark, correct?</b></p> <p>15 MR. ORENT: Objection.</p> <p>16 THE WITNESS: This is not correct. We</p> <p>17 could not see it in the images. I can tell you</p> <p>18 that in some specimens I did not see bark.</p> <p>19 BY MR. THOMAS:</p> <p>20 <b>Q. How do you report that?</b></p> <p>21 A. I report that I don't see it. I</p> <p>22 have cases when I reported that I don't see a bark.</p> <p>23 <b>Q. And you reported here that you had</b></p> <p>24 <b>two specimens where the degradation layer was not</b></p> <p>25 <b>visible where a hernia mesh and a sling were</b></p>

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<p>1 removed at three and ten months.</p> <p>2 Are those the only two times you</p> <p>3 haven't been able to see a bark?</p> <p>4 A. At that time, the only two. Since</p> <p>5 then I've seen a couple of more cases where I</p> <p>6 couldn't identify bark.</p> <p>7 Q. Any of those medical-legal cases?</p> <p>8 A. No, I think it was all hernia</p> <p>9 meshes, not medical-legal cases.</p> <p>10 Q. Do you have those slides</p> <p>11 available?</p> <p>12 MR. ORENT: Objection.</p> <p>13 THE WITNESS: Yes, I do, but they are</p> <p>14 of patients.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. You can't produce those to me if I</p> <p>17 asked you for them?</p> <p>18 A. I can't produce them.</p> <p>19 Q. Did the slides where there was no</p> <p>20 degradation bark, if you will, present contain</p> <p>21 inflammation?</p> <p>22 A. Yes, they did.</p> <p>23 Q. Were they removed because of pain?</p> <p>24 A. Yes. I think one of them was</p> <p>25 removed for erosion with pain. The other one, the</p>	<p>1 part of research project.</p> <p>2 Q. Well, have you produced that to us</p> <p>3 before?</p> <p>4 A. I don't know.</p> <p>5 Q. Okay. But just to make sure I got</p> <p>6 a clean answer. In all the work that you've done</p> <p>7 on all the Ethicon meshes, the only Ethicon mesh</p> <p>8 that you've analyzed by transmission electron</p> <p>9 microscopy is a mesh of a St. Michael's patient</p> <p>10 that's either a TVT or a Prolift, you don't know</p> <p>11 which?</p> <p>12 A. Now I'm not sure if it was St.</p> <p>13 Michael's or it was a medical-legal case. I don't</p> <p>14 remember now.</p> <p>15 Q. Okay?</p> <p>16 A. I would have to check, but if it</p> <p>17 was, it was the only case. I could do only one</p> <p>18 case of Ethicon mesh by transmission electron</p> <p>19 microscopy.</p> <p>20 Q. And why have you not conducted</p> <p>21 transmission electron microscopy on other meshes?</p> <p>22 A. There was no need. It is a really</p> <p>23 cumbersome, difficult and --</p> <p>24 Q. Does St. Michael's have that kind</p> <p>25 of equipment?</p>
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<p>1 hernia mesh, was removed just for pain.</p> <p>2 Q. On page 6 of the study, you</p> <p>3 describe that you use transmission electron</p> <p>4 microscopy --</p> <p>5 A. That's correct.</p> <p>6 Q. -- to study the ultra structural</p> <p>7 organization of the degraded layer in</p> <p>8 cross-sections?</p> <p>9 A. That's correct.</p> <p>10 Q. Did you use the TEM to study any</p> <p>11 TVT device?</p> <p>12 A. One. It was one Ethicon device,</p> <p>13 TVT or Prolift, I don't remember. I think it was a</p> <p>14 TVT.</p> <p>15 Q. Have you produced that work to us</p> <p>16 before?</p> <p>17 A. It's a St. Michael's Hospital</p> <p>18 patient.</p> <p>19 Q. Okay. So, is it fair to</p> <p>20 understand that the only transmission electron</p> <p>21 microscopy analysis that you've done on an Ethicon</p> <p>22 mesh is the St. Michael's patient that you can't</p> <p>23 produce to us?</p> <p>24 A. Well, it was a part of research.</p> <p>25 So if it was included in images, it was included as</p>	<p>1 A. Yes, we do. Otherwise, I wouldn't</p> <p>2 be able to do it. It's really expensive to do it</p> <p>3 somewhere outside.</p> <p>4 Q. Did you have to pay St. Michael's</p> <p>5 to do this?</p> <p>6 A. No, it's just part of our academic</p> <p>7 work.</p> <p>8 Q. Are you able to do this yourself</p> <p>9 or does somebody have to do it for you?</p> <p>10 A. I'm trained to do transmission</p> <p>11 electron microscopy. I mean, technicians prepare</p> <p>12 slides. It's usual, the same as for histology.</p> <p>13 But I do examination myself.</p> <p>14 Most of the transmission electron</p> <p>15 microscopy samples are with hernia meshes.</p> <p>16 Q. Page 10 there is a discussion of</p> <p>17 the clinical significance of polypropylene</p> <p>18 degradation?</p> <p>19 MR. ORENT: Are we going back to the</p> <p>20 report or saying on the study?</p> <p>21 MR. THOMAS: I'm on the study, sorry.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Page 10 on Exhibit 6, "Clinical</p> <p>25 Significance of Polypropylene Degradation".</p>

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<p style="text-align: right;">Page 290</p> <p>1 <b>Who drafted this section?</b></p> <p>2 A. Mostly me, partially my coauthors.</p> <p>3 <b>Q. Dr. Bendavid?</b></p> <p>4 A. Yes. And well, mostly Dr.</p> <p>5 Bendavid. I mean, I drafted most of it, but I was</p> <p>6 getting some corrections or changes, and the</p> <p>7 changes were coming mostly from Dr. Bendavid.</p> <p>8 <b>Q. Exhibits 5 and 6, you stand by the</b></p> <p>9 <b>findings stated in each of those articles?</b></p> <p>10 A. Yes, I am.</p> <p>11 <b>Q. Do you have depositions scheduled</b></p> <p>12 <b>in the next month?</b></p> <p>13 A. I'm not sure if I can disclose</p> <p>14 that.</p> <p>15 <b>Q. Do you have trial responsibilities</b></p> <p>16 <b>in the next month?</b></p> <p>17 A. Pardon?</p> <p>18 <b>Q. Do you have any trial</b></p> <p>19 <b>responsibilities in the next month?</b></p> <p>20 A. No, I don't think so.</p> <p>21 <b>Q. Your next trial is a December</b></p> <p>22 <b>trial with Ethicon?</b></p> <p>23 A. I'm not sure if I can disclose</p> <p>24 that either.</p> <p>25 <b>Q. Are you choosing not to?</b></p>	<p style="text-align: right;">Page 292</p> <p>1 BY MR. THOMAS:</p> <p>2 <b>Q. Do you have any set dates for any</b></p> <p>3 <b>trials between now and the Ethicon trial?</b></p> <p>4 A. No. Again, nothing set firmly.</p> <p>5 <b>Q. Okay.</b></p> <p>6 MR. ORENT: Just a sec. In addition to</p> <p>7 that, I think in the Cantrell matter I've been</p> <p>8 working with Kelly Crawford to schedule, I would</p> <p>9 imagine that would be within the next month.</p> <p>10 That's an Ethicon case, obviously.</p> <p>11 MR. THOMAS: Yes, I know about that.</p> <p>12 Hang on. Getting close to the end.</p> <p>13 -- OFF THE RECORD DISCUSSION --</p> <p>14 BY MR. THOMAS:</p> <p>15 <b>Q. Doctor, I'm told that the</b></p> <p>16 <b>information supplied to us concerning the eyepiece</b></p> <p>17 <b>micrometer measurements of the bark layers is</b></p> <p>18 <b>expressed in a single value as opposed to the four</b></p> <p>19 <b>individual measurements?</b></p> <p>20 A. No, it's a median, I told you</p> <p>21 that, then I pick median value out of four.</p> <p>22 <b>Q. Okay.</b></p> <p>23 A. It is described in the paper. So</p> <p>24 the volume which goes for analysis is a median one,</p> <p>25 which is more frequent.</p>
<p style="text-align: right;">Page 291</p> <p>1 A. There might be more and earlier, I</p> <p>2 don't want to disclose that. I'm not sure if I</p> <p>3 can, if I legally can disclose it.</p> <p>4 I mean, if it's not for Ethicon cases.</p> <p>5 For Ethicon I would disclose, but if it's not then</p> <p>6 I cannot disclose.</p> <p>7 MR. THOMAS: Counsel, there's no legal</p> <p>8 prohibition for him saying it?</p> <p>9 MR. ORENT: You can answer.</p> <p>10 THE WITNESS: They said that --</p> <p>11 MR. ORENT: Wait, hold on. They said</p> <p>12 is not an answer. So any communications that</p> <p>13 you've had are covered by a privilege. So what</p> <p>14 he's asking specifically are, if anything is firm</p> <p>15 in terms of a date that you know of, so --</p> <p>16 BY MR. THOMAS:</p> <p>17 <b>Q. For depositions or trial?</b></p> <p>18 MR. ORENT: For depositions or trial,</p> <p>19 not any communications about we might do this or</p> <p>20 might do that. But anything firm that you know you</p> <p>21 have a date set for.</p> <p>22 THE WITNESS: Then everything is</p> <p>23 changing. I have a set date one deposition. But</p> <p>24 the rest is still in the air.</p> <p>25</p>	<p style="text-align: right;">Page 293</p> <p>1 <b>Q. Do you have the four measurements</b></p> <p>2 <b>that you made or did you just pick the -- do you</b></p> <p>3 <b>have that as a part of your data set?</b></p> <p>4 A. I just measure them and right</p> <p>5 there I know how frequent is this measurement or</p> <p>6 that. So I don't have to put in the paper.</p> <p>7 <b>Q. Did you write down or keep a copy</b></p> <p>8 <b>of the four individual measurements that you made</b></p> <p>9 <b>of the --</b></p> <p>10 A. No, no. The methodology is check</p> <p>11 four spots. I see three, four, four, four, then</p> <p>12 four is the winner, so then four goes in the</p> <p>13 record.</p> <p>14 <b>Q. Did you produce your bills today</b></p> <p>15 <b>for the time that you spent in this case?</b></p> <p>16 A. In this case?</p> <p>17 <b>Q. In this case?</b></p> <p>18 A. Oh, in this. I had billing done</p> <p>19 for the -- for the report, it's in the folder.</p> <p>20 <b>Q. Do you recall how much time and</b></p> <p>21 <b>money you've spent on preparing the report in this</b></p> <p>22 <b>case, Exhibit 3 and 4?</b></p> <p>23 A. No, I don't.</p> <p>24 <b>Q. The invoice that you produced to</b></p> <p>25 <b>us on a thumb drive suggests that you have a</b></p>

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<p>1 balance, professional services August 14th, 2 August 24th for a total of \$8,550 -- 3 A. Sounds right. 4 <b>Q. -- is that right?</b> 5 <b>Doctor, I don't see -- I see general</b> 6 <b>part text revision; what does that mean?</b> 7 A. Revision of the general part. 8 <b>Q. General party report?</b> 9 A. Yes. 10 <b>Q. This report is the first time that</b> 11 <b>you reviewed any Ethicon documents or Ethicon</b> 12 <b>depositions, true?</b> 13 A. No, there was another case. 14 <b>Q. I didn't see it in any of your</b> 15 <b>reports before where you reviewed Ethicon</b> 16 <b>depositions and Ethicon documents?</b> 17 MR. ORENT: One moment. 18 BY MR. THOMAS: 19 <b>Q. The only other case it could be</b> 20 <b>would be the Bellew case?</b> 21 MR. ORENT: The doctor has not 22 testified previously about these issues. I don't 23 know whether or not there has been another report 24 on another matter disclosed. 25 It may very well be that there is</p>	<p>1 MR. ORENT: Why don't we take two 2 minutes. I'll going to have probably about ten 3 minutes worth of questions. 4 -- RECESS TAKEN AT 4:52 -- 5 -- UPON RESUMING AT 4:55 -- 6 CROSS-EXAMINATION BY MR. ORENT: 7 <b>Q. Good afternoon, Doctor.</b> 8 A. Good afternoon. 9 <b>Q. Earlier today you were asked a</b> 10 <b>number of questions about each of the</b> 11 <b>photomicrographs that we looked at, and one of the</b> 12 <b>predicate questions that you were asked for each</b> 13 <b>one was whether or not it was a TVT or a TVT-O; do</b> 14 <b>you recall being asked that series of questions?</b> 15 A. Yes, I do. 16 <b>Q. For purposes of your work does it</b> 17 <b>make any difference whether or not the product is</b> 18 <b>the TVT or TVT-O in terms of your findings as</b> 19 <b>reported here?</b> 20 A. No, it's the same sling, the same 21 mesh. The only difference is how it's placed and 22 the other components which come in the kit. 23 <b>Q. So if I understand your testimony,</b> 24 <b>is it your testimony that the TVT and the TVT-O --</b> 25 <b>the actual mesh device is the exact same?</b></p>
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<p>1 something that's still work product and not been 2 disclosed. So I don't want to get into the details 3 of that other potential matter. 4 BY MR. THOMAS: 5 <b>Q. Let me just ask it this way: The</b> 6 <b>bills that you've submitted to counsel in this</b> 7 <b>matter do not reflect any charges for time that</b> 8 <b>you've spent reviewing Ethicon documents or</b> 9 <b>depositions, correct?</b> 10 A. Partially, they do. I reviewed 11 some of that again; it's been drafted earlier. 12 MR. ORENT: Counsel, just to speed this 13 area up to the extent that it's not clear on the 14 bills, I think what we can do is we can supplement 15 by letter. 16 MR. THOMAS: That would be fine. I'm 17 not interested in getting anybody. I just want -- 18 MR. ORENT: I think what we'll do is we 19 can figure out the amount of time. 20 MR. THOMAS: I just want to make sure 21 you get paid for your time. You have to send your 22 bills and get paid. 23 Okay, that's all the questions I have, 24 Doctor. Thank you. 25 THE WITNESS: Thank you.</p>	<p>1 A. Exactly the same. 2 <b>Q. Okay. And so in terms of the</b> 3 <b>pathological findings that you make, as reported in</b> 4 <b>your report and your supplement, is there a -- is</b> 5 <b>there any reason for making a distinction between</b> 6 <b>the two devices?</b> 7 MR. THOMAS: Object to the form of the 8 question. 9 THE WITNESS: No. The only difference 10 is there can be more frequent occurrences of 11 striated muscle in the TVT-O samples than in TVT, 12 but it can be seen in both. 13 BY MR. ORENT: 14 <b>Q. And is that because of the</b> 15 <b>implantation route?</b> 16 A. That's correct. 17 <b>Q. And both devices are made of</b> 18 <b>Prolene mesh; is that correct?</b> 19 A. That is correct. 20 <b>Q. Now every one of the</b> 21 <b>photomicrographs that appear in Exhibits 1 and 2 to</b> 22 <b>today's deposition, that is your report and</b> 23 <b>supplemental report, did every one of those</b> 24 <b>photomicrographs appear either from prior expert</b> 25 <b>reports in Ethicon litigation, in the specific</b></p>

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<p style="text-align: right;">Page 298</p> <p>1 pathology of the consolidated plaintiffs, or in</p> <p>2 peer-reviewed medical literature written by you?</p> <p>3 A. That's correct. These are the</p> <p>4 three sources.</p> <p>5 Q. And you've been asked questions</p> <p>6 today about identifying various -- what you called</p> <p>7 additional TVT cases in your report; do you recall</p> <p>8 those questions?</p> <p>9 A. Yes, I do.</p> <p>10 Q. Did you produce photomicrographs</p> <p>11 of the additional TVT cases in the course of other</p> <p>12 reports you've provided in TVT cases?</p> <p>13 A. Yes, I did.</p> <p>14 Q. Now, with regard to the opinions</p> <p>15 that you express in your expert report in this</p> <p>16 case, and your supplement, do you use the same</p> <p>17 methodology that you have previously used when you</p> <p>18 testified in the western district -- excuse me, in</p> <p>19 the southern district of West Virginia?</p> <p>20 A. Yes, exactly the same methodology.</p> <p>21 Q. And is your -- the materials and</p> <p>22 your methodology that you utilized in this report</p> <p>23 the same methodology that you've used in other</p> <p>24 courts where you have been allowed to testify at</p> <p>25 trial?</p>	<p style="text-align: right;">Page 300</p> <p>1 device; is that correct?</p> <p>2 MR. THOMAS: Object to form.</p> <p>3 THE WITNESS: That is correct.</p> <p>4 BY MR. ORENT:</p> <p>5 Q. And why is it that you don't list</p> <p>6 a sample size or rate of error in your report?</p> <p>7 A. It's not the purpose. I'm not</p> <p>8 analyzing statistically frequency or rate of</p> <p>9 occurrence. I showed the changes which can occur.</p> <p>10 It's binary assessment; either it can occur or</p> <p>11 cannot occur. It can occur in one case, it can</p> <p>12 occur in 100 percent of cases, but it can happen.</p> <p>13 For a specific patient it either occurs or it</p> <p>14 doesn't.</p> <p>15 Q. In order to show that something</p> <p>16 can occur, in terms of a failure mode, is there a</p> <p>17 sample size, a minimum sample size that you have</p> <p>18 need to show that a failure rate or failure mode</p> <p>19 can occur?</p> <p>20 MR. THOMAS: Object to form.</p> <p>21 THE WITNESS: One case is enough. If</p> <p>22 it can occur in one case, it can occur again.</p> <p>23 BY MR. ORENT:</p> <p>24 Q. And these concepts of sample size</p> <p>25 with one being enough to prove capability, is that</p>
<p style="text-align: right;">Page 299</p> <p>1 A. That's correct.</p> <p>2 Q. Did you use any different</p> <p>3 techniques in this report?</p> <p>4 A. No.</p> <p>5 Q. Okay. Now, the opinions that you</p> <p>6 testified to in this report, and in the supplement,</p> <p>7 are they identical to the opinions that you've</p> <p>8 previously provided in trial in matters before the</p> <p>9 southern district of West Virginia?</p> <p>10 A. Yes.</p> <p>11 MR. THOMAS: Object to form.</p> <p>12 THE WITNESS: That is correct. The</p> <p>13 same opinions.</p> <p>14 BY MR. ORENT:</p> <p>15 Q. Are they, the opinions that you</p> <p>16 express in your expert report and in the</p> <p>17 supplement, are they also identical to opinions</p> <p>18 that you have provided in other courts during</p> <p>19 trials throughout the country?</p> <p>20 MR. THOMAS: Object to form.</p> <p>21 THE WITNESS: That is correct.</p> <p>22 BY MR. ORENT:</p> <p>23 Q. And throughout the course of your</p> <p>24 report you provide just a few examples of a variety</p> <p>25 of failure modes associated with the TVT and TVT-O</p>	<p style="text-align: right;">Page 301</p> <p>1 something that's generally accepted in the medical</p> <p>2 community, in the scientific community?</p> <p>3 MR. THOMAS: Object to form.</p> <p>4 THE WITNESS: Yes. If you answer the</p> <p>5 question if it can occur, one case is enough.</p> <p>6 BY MR. ORENT:</p> <p>7 Q. Same thing with a binary</p> <p>8 observation; it either occurs or doesn't occur.</p> <p>9 There's no rate of error associated with that; is</p> <p>10 that correct?</p> <p>11 MR. THOMAS: Object to the form of the</p> <p>12 question.</p> <p>13 THE WITNESS: It's either there or it's</p> <p>14 not. It's either zero occurrence or 100 percent.</p> <p>15 BY MR. ORENT:</p> <p>16 Q. When you talk about using large</p> <p>17 enough sample sizes and large enough rates of</p> <p>18 error, is that only used when you actually try and</p> <p>19 extrapolate from a data set to an individual?</p> <p>20 MR. THOMAS: Object to the form of the</p> <p>21 question.</p> <p>22 THE WITNESS: That's used to predict</p> <p>23 specific rates of specific occurrence, and that's</p> <p>24 used in relation to a cohort of patients and</p> <p>25 devices. And it's a different question.</p>

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<p style="text-align: right;">Page 302</p> <p>1 BY MR. ORENT:</p> <p>2 <b>Q. Okay. And in terms of the</b></p> <p>3 <b>opinions that you provided here in your expert</b></p> <p>4 <b>report, do you hold each of those opinions to a</b></p> <p>5 <b>reasonable degree of medical and professional</b></p> <p>6 <b>certainty?</b></p> <p>7 A. Yes, I do.</p> <p>8 <b>Q. And with regard to the various</b></p> <p>9 <b>staining techniques that you've utilized, are each</b></p> <p>10 <b>one of those staining techniques peer-reviewed in</b></p> <p>11 <b>their own right?</b></p> <p>12 MR. THOMAS: Object to the form of the</p> <p>13 question.</p> <p>14 THE WITNESS: That is correct, yes.</p> <p>15 BY MR. ORENT:</p> <p>16 <b>Q. Has H&amp;E been utilized as a stain</b></p> <p>17 <b>and been peer-reviewed as a proper way of looking</b></p> <p>18 <b>at tissue for a significant period of time?</b></p> <p>19 A. Over 100 years, or over the course</p> <p>20 of 100 years.</p> <p>21 <b>Q. How about myeloperoxidase, has</b></p> <p>22 <b>that been peer-reviewed as use for staining?</b></p> <p>23 MR. THOMAS: Object to the form of the</p> <p>24 question.</p> <p>25 THE WITNESS: We have several decades</p>	<p style="text-align: right;">Page 304</p> <p>1 question.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. ORENT:</p> <p>4 <b>Q. Now, with regard to the work that</b></p> <p>5 <b>you've done here, none of these opinions are new;</b></p> <p>6 <b>is that right?</b></p> <p>7 MR. THOMAS: Object to the form of the</p> <p>8 question.</p> <p>9 THE WITNESS: That is correct.</p> <p>10 BY MR. ORENT:</p> <p>11 <b>Q. And in terms of the material that</b></p> <p>12 <b>you've produced on disk. Having provided to</b></p> <p>13 <b>counsel today, did you produce all non-confidential</b></p> <p>14 <b>materials that you could provide?</b></p> <p>15 A. Yes. I selected that I could</p> <p>16 safely release.</p> <p>17 <b>Q. You were also asked a number of</b></p> <p>18 <b>questions about the peer review and peer-review</b></p> <p>19 <b>process; do you recall those questions?</b></p> <p>20 A. Yes, I do.</p> <p>21 <b>Q. As an academic, do you have</b></p> <p>22 <b>concerns about maintaining the integrity of the</b></p> <p>23 <b>peer-review process?</b></p> <p>24 A. Could you repeat the question.</p> <p>25 <b>Q. Sure. As an academic, as an</b></p>
<p style="text-align: right;">Page 303</p> <p>1 of use.</p> <p>2 BY MR. ORENT:</p> <p>3 <b>Q. And how about S100?</b></p> <p>4 MR. THOMAS: Object to the form of the</p> <p>5 question.</p> <p>6 THE WITNESS: Same thing. It's been</p> <p>7 used since late '70s, early '80s.</p> <p>8 BY MR. ORENT:</p> <p>9 <b>Q. What about the use of polarizing</b></p> <p>10 <b>light, is that something that's peer-reviewed and</b></p> <p>11 <b>accepted in the identification of crystalline</b></p> <p>12 <b>substances?</b></p> <p>13 A. It's been described for histology</p> <p>14 use from 1920s, and even I saw it's been used in</p> <p>15 Ethicon studies as well. Ethicon scientists were</p> <p>16 using polarized light as well. Well, let me</p> <p>17 rephrase that. Who came to the same conclusions I</p> <p>18 came.</p> <p>19 <b>Q. And with regard to the medical</b></p> <p>20 <b>peer-reviewed literature on mesh and mesh</b></p> <p>21 <b>complications, in fact, there's a group out of the</b></p> <p>22 <b>University of Michigan that published utilizing</b></p> <p>23 <b>some of the same techniques that you've described</b></p> <p>24 <b>in your report; is that correct?</b></p> <p>25 MR. THOMAS: Object to the form of the</p>	<p style="text-align: right;">Page 305</p> <p>1 <b>author and a researcher, are there important</b></p> <p>2 <b>reasons why the confidentiality of the</b></p> <p>3 <b>peer-review process needs to be maintained?</b></p> <p>4 A. Yes. I mean, especially when</p> <p>5 there is an involvement of a manufacturer, because</p> <p>6 I mean, this is major concern.</p> <p>7 Most publications -- journals, they</p> <p>8 require, the first thing they need to have</p> <p>9 submitted, has it been funded by industry, by</p> <p>10 manufacturers. So it's a major concern to try to</p> <p>11 be independent from manufacturers.</p> <p>12 MR. ORENT: All right, Doctor, thank</p> <p>13 you very much. I have no further questions.</p> <p>14 MR. THOMAS: Thank you, Doctor, for</p> <p>15 your time.</p> <p>16</p> <p>17</p> <p>18 -- Whereupon the deposition concluded at 5:05 p.m.</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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1 REPORTER'S CERTIFICATE	1 INSTRUCTIONS TO WITNESS
2	2
3	3
4 I, JUDITH M. CAPUTO, RPR, CSR, CRR,	4 Read your deposition over carefully.
5 Registered Professional Reporter, certify;	5 It is your right to read your deposition and make
6 That the foregoing proceedings were	6 changes in form or substance. You should assign a
7 taken before me at the time and place therein set	7 reason in the appropriate column on the erratum
8 forth, at which time the witness was put under oath	8 sheet for any change made.
9 by me;	9 After making any changes in form or
10 That the testimony of the witness and	10 substance, and which have been noted on the
11 all objections made at the time of the examination	11 following erratum sheet, along with the reason for
12 were recorded stenographically by me and were	12 any change, sign your name on the erratum sheet and
13 thereafter transcribed;	13 date it.
14 That the foregoing is a true and	14 Then sign your deposition at the end of
15 correct transcript of my shorthand notes so taken.	15 Your testimony in the space provided. You are
16	16 signing it subject to the changes you have made in
17	17 the erratum sheet, which will be attached to the
18	18 deposition before filing. You must sign it in
19 Dated this 14th day of September, 2015.	19 front of a witness. The witness need not be a
20	20 notary public. Any competent adult may witness
21	21 your signature.
22	22 Return the original erratum sheet
23	23 promptly. Court rules require filing within 30
24 PER: JUDITH CAPUTO, RPR, CSR, CRR	24 days after you receive the deposition.
25	25
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1 CERTIFICATE OF REPORTER	1 ** ERRATA SHEET **
2 CANADA )	2
3 PROVINCE OF ONTARIO )	3 NAME OF CASE: TERRESKI MULLINS, ET AL. V.
4	4 ETHICON, INC., ET AL.
5 I, Judith M. Caputo, the officer before whom the	5 DATE OF DEPOSITION: SEPTEMBER 14th, 2015
6 foregoing deposition was taken, do hereby certify	6 NAME OF WITNESS: VLADIMIR IAKOVLEV
7 that the witness whose testimony appears in the	7
8 foregoing deposition was duly sworn by me; that the	8
9 testimony of said witness was taken by me in	9 PAGE LINE FROM TO
10 shorthand, using Computer Aided Realtime, to the	10
11 best of my ability and thereafter reduced to	11
12 written format under my direction; that I am	12
13 neither counsel for, related to, nor employed by	13
14 any of the parties to the action in which the	14
15 deposition was taken, and further that I am not	15
16 related or any employee of any attorney or counsel	16
17 employed by the parties thereto, nor financially or	17
18 otherwise interested in the outcome of the action.	18
19	19
20	20
21	21
22 Judith M. Caputo, RPR, CSR, CRR	22
23	23
24 Commissioner for taking	24
25 Oaths in the Province of Ontario	25 VLADIMIR IAKOVLEV

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<p style="text-align: right;">Page 310</p> <p>1 PROVINCE OF ONTARIO )  2 TORONTO REGION )  3  4  5 I, the undersigned, declare under  6 penalty of perjury that I have read the foregoing  7 transcript, and I have made any corrections,  8 additions or deletions that I was desirous of  9 making;  10 That the foregoing is a true and  11 correct transcript of my testimony contained  12 therein.  13  14 _____  15 VLADIMIR IAKOVLEV, M.D.  16  17  18 Subscribed and sworn to before me this ____  19 Day of _____, 2015 at  20 _____,  21 (City) (Province)  22  23 _____  24 (Notary Public)  25 My Commission Expires: _____</p>	

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# EXHIBIT R

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

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DIANNE M. BELLEW,	:	
Plaintiff,	:	CASE NUMBER
v.	:	2:13-cv-22473
ETHICON, INC.,	:	
ETHICON, LLC, and	:	
JOHNSON & JOHNSON,	:	
Defendants.	:	

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TRANSCRIPT OF TRIAL DAY 4

MARCH 05, 2015

BEFORE THE HONORABLE JOSEPH R. GOODWIN,  
UNITED STATES DISTRICT JUDGE

Court Reporters:	Carol Farrell, CRR, RMR, CCP, RPR (304)347-3188 carol_farrell@wvsd.uscourts.gov
	Lisa A. Cook, RPR, RMR, CRR, FCRR (304)347-3198 lisa_cook@wvsd.uscourts.gov

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produced by computer.



## 1 A P P E A R A N C E S

## 2 FOR THE PLAINTIFFS:

3 BRYAN F. AYLSTOCK, ESQUIRE  
 4 DANIEL J. THORNBURGH, ESQUIRE  
 5 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC  
 6 17 East Main Street, Suite 200  
 7 Pensacola, FL 32502  
 8 BENJAMIN H. ANDERSON, ESQUIRE  
 9 ANDERSON LAW OFFICES, LLC  
 10 1360 W. 9th Street, Suite 215  
 11 Cleveland, OH 44113

12 ADAM M. SLATER, ESQUIRE  
 13 MAZIE SLATER KATZ & FREEMAN, LLC  
 14 103 Eisenhower Parkway  
 15 Roseland, NJ 07068  
 16 JEFFREY S. GRAND, ESQUIRE  
 17 BERNSTEIN LIEBHARD LLP  
 18 10 East 40th Street, 22nd Floor  
 19 New York, NY 10016

## 20 FOR THE DEFENDANTS:

21 CHRISTY D. JONES, ESQUIRE  
 22 BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC  
 23 1020 Highland Colony Parkway, Suite 1400  
 24 Ridgeland, MS 39157

25 DAVID B. THOMAS, ESQUIRE  
 THOMAS COMBS & SPANN, PLLC  
 PO Box 3824  
 Charleston, WV 25338-3824

1 PROCEEDINGS had before The Honorable Joseph R.

2 Goodwin, District Judge, United States District Court,  
 3 Southern District of West Virginia, in Charleston, West  
 4 Virginia, on March 05, 2015, as follows:

5 (The Jury entered the courtroom at 9:06 a.m.)

6 THE OFFICER: All rise.

7 THE COURT: Good morning.

8 RESPONSE: Good morning, Your Honor.

9 THE COURT: Can you tell that John has been opening  
 10 court for more than one time?

11 (Laughter.)

12 THE COURT: I trust you had a pleasant evening, if

13 not a necessarily pleasant transition from your place of  
 14 lodging to here. I knew we could all make it and we all did.

15 I have this theory about -- if I may waste a minute of your  
 16 time, and, timekeeper, you can deduct this. I have a theory

17 that if the news media goes crazy and says it's going to be  
 18 awful and you can't possibly move and go immediately to your

19 homes and hide under the bed, that it's not going to be bad at  
 20 all; that the times that it's really bad is when it catches us

21 all by surprise and we don't even know it.

22 I just -- some of you are old enough to remember when

23 Governor Rockefeller declared a blizzard was coming and we all  
 24 went to our homes and there was nothing but blue sky.

25 (Laughter.)

## 1 I N D E X

## 2 Direct Cross Redirect Recross

## 3 WITNESSES FOR

## 4 THE PLAINTIFF

5 GENE KAMMERER (video) 616  
 6 (Continued)

7 VLADIMIR IAKOVLEV 617 671 705

8 VINCENT LUCENTE (video) 709

9 SCOTT CIARROCCA (video) 711

10 SEAN O'BRYAN (video) 712 712 713

11 CHARLOTTE OWENS 713 714

12 KIMBERLY HUNSICKER 715

13 CAROL DEHASSE 717 718

14 BRYAN LISA 724

1 THE COURT: And he never lived it down. It was and  
 2 will be remembered by anybody old enough as the Rockefeller  
 3 blizzard. I don't think there was a quarter of an inch of  
 4 snow.

5 All right. We're ready to resume. Call your next  
 6 witness.

7 MR. THOMAS: Your Honor, defendants will continue  
 8 with the examination of Gene Kammerer.

9 THE COURT: Oh, that's right, we've got  
 10 cross-examination.

11 MR. THOMAS: Yes, Your Honor. Thank you.

12 THE COURT: Very well.

13 (The videotaped cross-examination testimony of  
 14 Dr. Gene Kammerer was played for the jury from 9:10 a.m. to  
 15 9:19 a.m.)

16 MR. THOMAS: That's the cross-examination, Your  
 17 Honor.

18 THE COURT: Is there any redirect?

19 MR. SLATER: There is none, Your Honor.

20 THE COURT: Any exhibits?

21 MR. THOMAS: No, Your Honor.

22 THE COURT: Call your next witness.

23 MR. ANDERSON: Yes, Your Honor. At this time  
 24 plaintiffs called Dr. Vladimir Iakovlev.

25 THE COURT: Doctor?

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1 THE DEPUTY CLERK: If you'll raise your right hand.  
2 (VLADAMIR IAKOVLEV, HAVING BEEN DULY SWORN, TESTIFIED AS  
3 FOLLOWS:)  
4 THE WITNESS: Yes, I do.  
5 THE DEPUTY CLERK: Thank you. Please take the  
6 witness stand.  
7 (DIRECT EXAMINATION OF VLADIMIR IAKOVLEV BY MR. ANDERSON:)  
8 Q. Good morning.  
9 A. Good morning. Is it on?  
10 THE DEPUTY CLERK: Oh, it's over here. No, it's not  
11 on.  
12 THE WITNESS: I think you just need to increase the  
13 volume.  
14 THE COURT: No, we need to get the microphone in  
15 front of him.  
16 THE DEPUTY CLERK: He has a lapel mic on.  
17 THE COURT: Well, somebody else can do that. Have  
18 you got it? Okay. Got your own microphone, good.  
19 BY MR. ANDERSON:  
20 Q. Okay. Take two. Good morning.  
21 A. Good morning.  
22 Q. What is your -- what is your name, please?  
23 A. Vladimir Iakovlev.  
24 Q. And what is your occupation?  
25 A. I am a medical doctor.

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1 Q. Do you have a subspecialty?  
2 A. I'm a pathologist.  
3 Q. And what is pathology?  
4 A. Pathology is laboratory medicine. It's in the lab, in  
5 the hospital. Pathologists work in the lab and receive  
6 samples from the patients. This would be fluids like blood,  
7 like urine, and tissue samples like cells and biopsies. We  
8 analyze the samples, we come up with the diagnosis, and we  
9 report this diagnosis for further treatment of the patients.  
10 Q. Do you have a particular focus within pathology?  
11 A. I am an anatomic pathologist.  
12 Q. Anatomic pathologist?  
13 A. Anatomic pathologist.  
14 Q. And what is anatomic pathology?  
15 A. Anatomic pathology is the field of pathology where we  
16 analyze tissue samples, not fluids like blood, but tissue  
17 samples, create cells like Pap smears, tissue samples such as  
18 biopsies, or large resections, like a breast resection or  
19 stomach resection or we do the whole body, we do autopsy.  
20 Q. You are saying resection. What is a resection?  
21 A. Resection, when surgeons cut out part of the organ, part  
22 of the colon or part of the stomach or from the breast.  
23 Q. Are you familiar with a term in medicine known as a  
24 "differential diagnosis"?  
25 A. Yes.

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1 Q. Is that something that you, as an anatomic pathologist,  
2 use in your daily practice?  
3 A. Yes.  
4 Q. Can you please explain that to the jury?  
5 A. Differential diagnosis is basic -- basic principle in  
6 medicine to arrive at a diagnosis. When the patient comes to  
7 the hospital with some problem, medical doctors examine, so  
8 they have their differential diagnosis, medical diseases on  
9 the differential diagnosis.  
10 Q. Go a little slower, if you would, please.  
11 A. Multiple diseases are differential diagnosis. The  
12 differential diagnosis --  
13 THE COURT: I couldn't understand you. I'm sorry.  
14 Say it again.  
15 BY MR. ANDERSON:  
16 Q. Just go a little slower, okay? And a little louder.  
17 A. Differential diagnosis is multiple diseases.  
18 When the patient comes to the hospital, they present  
19 with a problem, and after -- after examination, clinicians  
20 have several diseases in their mind which can cause these  
21 problems. And then they order tests, including taking  
22 samples, and send them to pathology.  
23 When it comes to me, I have my differential diagnosis,  
24 depending on what I see in the microscope. And then I do my  
25 investigation, like medical investigation, and then I narrow

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1 down this even further. From many diseases, we go down to  
2 one, which is the right one.  
3 Q. Is that something that you do every day in your practice  
4 as a pathologist?  
5 A. Yes.  
6 Q. And is that something that you did in arriving at your  
7 opinions and your expert conclusions in this matter?  
8 A. Yes.  
9 MR. ANDERSON: Your Honor, may I approach?  
10 THE COURT: You may.  
11 BY MR. ANDERSON:  
12 Q. Dr. Iakovlev, I'm showing you what has been marked as  
13 plaintiff's Exhibit P-2258. Can you please just identify that  
14 for the record?  
15 A. This is my curriculum vitae.  
16 Q. And what is a curriculum vitae?  
17 A. This is a description of my career or my education or my  
18 work and my publications.  
19 Q. Okay. And you have it there in front of you in case you  
20 need to refer to it during this part of your testimony, where  
21 I'm just going to go through your background and training and  
22 education. Okay?  
23 A. Okay.  
24 Q. Where do you currently work?  
25 A. I work at St. Michael's Hospital, that's in Toronto,

1 Canada.

2 Q. What's your current position?

3 A. I am the director of cytopathology and I am an anatomic

4 pathologist.

5 Q. How long have you been at St. Michael's?

6 A. About eight years.

7 Q. And what is cytopathology?

8 A. Cytopathology is the part of anatomic pathology where we

9 examine cells.

10 Q. Slow down a little.

11 Okay. You examine cells. Go ahead.

12 A. Cells. Not larger pieces of tissue, but cells, which are

13 scraped off like Pap smears or aspirated through a fine,

14 really thin needle.

15 Q. Explain to the jury what you do on a day-to-day basis at

16 St. Michael's as an anatomic pathologist.

17 A. As an anatomic pathologist, I examine tissue samples.

18 Surgeons and radiologists and other clinicians take tissue

19 samples from the patient, then they send them to the lab.

20 When we receive them at the lab, we examine them first by

21 naked eye, grossly, and by feeling them with our fingers.

22 Then we take sections from those samples for microscopy, send

23 them to the histotechnologists, they make glass slides like

24 this, and then we examine them under the microscope.

25 Q. Are you familiar with the term clinicopathological

1 correlation?

2 A. Yes.

3 Q. Okay. What is that term to you as a pathologist?

4 A. Clinicopathological correlation is when I correlate

5 medical history, radiological appearance, and my pathology

6 findings. I put everything together, like pieces in jigsaw

7 puzzle, to show the big picture and to arrive with a correct

8 diagnosis.

9 Q. Briefly describe for the jury, please, your education and

10 training that prepared you to work as a pathologist.

11 A. To become a pathologist, one needs to go through medical

12 school. I did my medical training in Russia. At that time

13 the system there was similar to United Kingdom. You can

14 either go directly from high school or you can do first

15 college degree and then apply to medical school. I did my

16 volunteer work at the hospital ward, I attended anatomy

17 scientific society, and I passed my entrance exams with high

18 marks, and I was accepted directly from high school.

19 After graduation of the medical school, it was time of

20 great struggle. That was early '90s. The government didn't

21 have money, didn't care much, didn't invest money in the

22 medical system. And we wanted to build our careers to do

23 research.

24 At the same time I remembered how my mother traveled to

25 Canada in early '80s, so the logical thought was to immigrate

1 to Canada. We applied for immigration and we got our

2 immigration papers in a year.

3 When we came to Canada, we took our licensing exams,

4 medical licensing exams in Canada and United States, and I

5 applied for anatomic pathology residency and was accepted at

6 the University of Manitoba.

7 Q. Where do you hold medical licenses?

8 A. I hold medical licenses in the Province of Ontario,

9 Toronto, and State of Michigan, U.S.A.

10 Q. Are you board certified in any fields?

11 A. Yes. I am board certified for anatomic pathology, by the

12 Royal College of Physicians and Surgeons of Canada, and by

13 American Board of Pathology.

14 Q. How does one obtain board certification, just briefly?

15 A. You submit all your education and training, they evaluate

16 if it's sufficient and then you take exam. If you pass the

17 exam, you obtain your certification.

18 Q. Do you have to retake the board certification test?

19 A. Yes. I have to retake the American Board of Pathology

20 exam every ten years. This was a relatively recent decision

21 because the field was changing so fast that if the

22 pathologists were not updating their knowledge, they would not

23 be able to deliver the same standard of care.

24 Q. Slow down just a little bit if you would.

25 As a current practicing pathologist, are you required

1 to complete continuing medical education courses in your

2 field?

3 A. Yes. That's another initiative, to stimulate

4 pathologists to update their knowledge. The American Board of

5 Pathology, I need to submit every two years specific number of

6 hours of courses and conferences and also meeting exams. And

7 the same thing for Royal College of Physicians and Surgeons of

8 Canada, I have to submit this information every year.

9 Q. Are you currently a member of any professional societies

10 in your field?

11 A. I am a fellow of Royal College of Physicians of Canada in

12 Anatomic Pathology, and I'm a fellow of College of American

13 Pathologists.

14 Q. Do you currently have any teaching responsibilities?

15 A. Yes. I am appointed as the director of laboratory

16 medicine at the University of Toronto, I teach medical

17 students, I teach residents, I teach fellows, I teach graduate

18 students, I also teach cytotechnologists, physiotherapists and

19 pathologists.

20 Q. What do your teaching duties entail?

21 A. For medical residents and medical students and also

22 fellows, I teach them every day handling the cases. When we

23 receive the specimens, we examine them together, and I teach

24 them rating the specimens or rating the slides, and then we

25 have formal sessions every week with residents. We teach them

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1 during one-hour sessions.

2 Q. Are those principles of differential diagnosis as well as  
3 clinicopathological correlation that you described to the jury  
4 something that you teach your students as well as the fellows  
5 and residents?

6 A. Of course, because this is the basis of medicine, we  
7 teach it from the very beginning.

8 Q. And are those principles that you applied in forming your  
9 expert conclusions and opinions in this case that you'll  
10 present to the Court and jury today?

11 A. Yes.

12 Q. Have you written articles that have been published in the  
13 scientific literature?

14 A. Yes. I published over 20 full-sized papers and over 30  
15 abstracts; also presented multiple lectures at national and  
16 international meetings.

17 Q. Do any of those articles or abstracts relate to your  
18 examination of explanted surgical meshes made out of  
19 polypropylene like the Prolift that we are here for today?

20 A. Yes. I published two full papers, three papers had  
21 submission, about ten abstracts, and also presented multiple  
22 presentations.

23 MR. ANDERSON: Your Honor, at this time plaintiffs  
24 would seek to move P-2258 into evidence.

25 MR. THOMAS: No objection, Your Honor.

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1 including the Prolift, typically sent to you by the surgeons  
2 who have removed them in the hospital?

3 A. Yes.

4 Q. Why do surgeons send explanted foreign bodies like  
5 medical devices and transvaginal meshes to you as an anatomic  
6 pathologist for your review?

7 THE COURT: Counsel?

8 MR. THOMAS: It calls for what the doctor -- I object  
9 to the question because he asked why the doctors sent things  
10 to him --

11 MR. ANDERSON: I can rephrase it, Your Honor.

12 THE COURT: All right.

13 BY MR. ANDERSON:

14 Q. What is the purpose of your -- strike that.

15 In your role as an anatomic pathologist at  
16 St. Michael's, what is the purpose of surgeons within the  
17 hospital sending to you explanted medical devices like  
18 polypropylene meshes from their patients?

19 A. Everything which is removed from the human body needs to  
20 be sent to pathology. We document it, describe it, describe  
21 gross features, how the device or foreign body looked, and  
22 then if we can take microscopic sections, we take microscopic  
23 sections and assess what's the state of the device itself and  
24 what is the state of the tissue around it, if the device  
25 failed on its own or there was another condition like a tumor

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1 THE COURT: It may be received.

2 MR. ANDERSON: Thank you, Your Honor.

3 (PLAINTIFF EXHIBIT P-2258 WAS RECEIVED IN EVIDENCE.)

4 BY MR. ANDERSON:

5 Q. Now, as part of your daily practice at St. Michael's, do  
6 you routinely receive foreign bodies or foreign materials like  
7 medical devices that have been removed from patients for which  
8 you have been asked to render medical diagnoses and opinions?

9 A. Yes, we routinely receive foreign bodies and medical  
10 devices. Foreign bodies can be foreign bodied embedded during  
11 trauma, during industrial accidents, and motor vehicle  
12 accidents.

13 Q. Slow down just a little, please, for the court reporter.  
14 Okay?

15 A. And medical devices also are removed when they fail.  
16 This would be breast implants, cardiac valves, hips, and knee  
17 implants, as well as surgical meshes.

18 Q. Have those explanted surgical meshes including meshes  
19 made of polypropylene for transvaginal repair?

20 A. Yes.

21 Q. Have you received surgically removed Prolift mesh to  
22 perform pathological analysis as your role as an anatomic  
23 pathologist at St. Michael's?

24 A. Yes.

25 Q. Are these explants, including transvaginal meshes and

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1 which made the device fail.

2 Q. At some point in time did I ask you to review materials  
3 in this case and to give your expert conclusions with regard  
4 to Dianne Bellew?

5 A. Yes.

6 Q. Did you do the same thing in this case that you do on a  
7 day-to-day, routine basis as an anatomical pathologist at  
8 St. Michael's when you receive explanted medical devices from  
9 the surgeons?

10 A. Yes.

11 Q. Were you provided materials to review specific to Dianne  
12 Bellew in this case?

13 A. Yes. I received medical records from the clinical chart  
14 and I received tissue samples excised from -- from  
15 Ms. Bellew's body.

16 Q. Okay. And what surgery were those explanted samples  
17 from?

18 A. It was July of 2012, the third surgery.

19 Q. For the record, just briefly summarize your understanding  
20 of Ms. Bellew's clinical course for the jury as it relates to  
21 the case and as it relates to your opinions in the case.

22 A. Ms. Bellew had placement of Prolift medical device in  
23 2009 for bladder prolapse. In about two years, she presented  
24 with bleeding and pain during intercourse. Initially, she was  
25 treated conservatively for vaginal dryness and atrophy. And

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1 this changed symptoms to some degree, but she came back in  
 2 about a month, and the examination showed that there was  
 3 palpable mesh which was tender on the left which was creating  
 4 left-sided pelvic pain, and the decision was to excise the  
 5 painful area. During surgery, it was found to be sclerotic  
 6 and hardened. It was excised, which gave some relief of the  
 7 symptoms, but Ms. Bellew came back, I think in about October,  
 8 with recurrence of the symptoms. There was more excision done  
 9 at that time, and, again, there was a period of relief or  
 10 improvement of the symptoms. But then she came back in a  
 11 year, and it was the same symptoms. Examination showed more  
 12 of hardened tender mesh. And then Dr. DeHasse proceeded for  
 13 large excision.  
 14 Q. And from that large excision in July, 2012, what's your  
 15 understanding of how many pieces of Prolift mesh were  
 16 surgically removed?  
 17 A. From the original pathology report, there was seven  
 18 pieces of the mesh removed.  
 19 Q. How many fragments of the mesh from that surgery were  
 20 made available for you to analyze?  
 21 A. Four.  
 22 Q. And did you analyze all four of them?  
 23 A. Yes, I analyzed all four.  
 24 Q. How did you receive the pieces of mesh that you analyzed  
 25 from Ms. Bellew's surgery in July, 2012?

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1 A. They came in a container with formalin.  
 2 Q. And what is formalin?  
 3 A. Formalin is basically formaldehyde. It is natural  
 4 fixative. It preserves tissue. It was discovered about a  
 5 hundred years ago and became standard preservative for tissue.  
 6 All those specimens you see in museums are preserved in  
 7 formalin. You preserve specimens in time. They don't  
 8 degrade, they don't decompose.  
 9 Q. And is the use of formalin in order to preserve tissue  
 10 standard in your industry for the preservation of explants  
 11 from people's bodies?  
 12 A. Yes.  
 13 Q. Other than receiving the container in formalin, what else  
 14 did you receive with -- if anything, with the surgical pieces  
 15 when you first received them?  
 16 A. The chain of custody and medical records.  
 17 Q. Did you photograph the explanted fragments that you had  
 18 available for you to analyze?  
 19 A. Yes.  
 20 MR. ANDERSON: Okay. Your Honor, may I approach?  
 21 THE COURT: You may.  
 22 BY MR. ANDERSON:  
 23 Q. I'm showing you what has been marked as P-1909. Can you  
 24 first, please, just identify that for the record?  
 25 A. This is the gross photograph of the specimen I received.

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1 Q. You said gross photograph and gross specimen a couple of  
 2 times. I just want to make the jury understands what those  
 3 terms are for a pathologist.  
 4 What do you mean by gross specimens, please?  
 5 A. Gross means by naked eye enhanced. Microscopic is what  
 6 we see in microscopy.  
 7 Q. Did you take this photograph?  
 8 A. Yes.  
 9 Q. Does this photograph that you took fairly and accurately  
 10 represent the Prolift mesh pieces as you received them?  
 11 A. Yes.  
 12 Q. Did you rely on this document in forming your opinions in  
 13 this case?  
 14 A. Yes.  
 15 Q. Is it significant to your opinions in this case?  
 16 A. Yes.  
 17 MR. ANDERSON: Your Honor, we would ask that we be  
 18 able to publish this to the jury and enter plaintiff's P-1909  
 19 in the record?  
 20 THE COURT: It may be admitted and published.  
 21 MR. ANDERSON: Thank you.  
 22 (PLAINTIFF EXHIBIT P-1909 WAS RECEIVED IN EVIDENCE.)  
 23 (The document was published to the jury.)  
 24 BY MR. ANDERSON:  
 25 Q. Please explain to the jury what we are seeing in

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1 plaintiff's 1909 in this photograph, Dr. Iakovlev.  
 2 A. There is identification of the surgical number, and I can  
 3 correlate it with the medical information system of  
 4 St. Michael's Hospital and can trace it and see this specimen  
 5 is from Ms. Bellew.  
 6 Also you can see there are four pieces, and please pay  
 7 attention here. There are blue threads inside this piece. We  
 8 will come back to these blue threads later.  
 9 Q. Can you remove the dots for a moment and can you blow up  
 10 the left-hand piece? You need to tap the screen, I think.  
 11 A. Yes, we can see the blue threads between the dots.  
 12 Q. What are those blue threads from, Dr. Iakovlev? What are  
 13 those blue threads from?  
 14 A. Those are blue threads of the Prolift device.  
 15 And another observation here, you see these blue  
 16 threads are not in line, like this. They have different  
 17 orientation, shows that mesh is not flat, even from gross --  
 18 gross appearance.  
 19 Q. As part of your pathological analysis of these pieces of  
 20 mesh, what did you do next?  
 21 A. I examined them with my fingers, I compared them to the  
 22 normal tissue, which is also fixed in formalin, and I found  
 23 that these pieces were hardened, and it was much thicker than  
 24 would be one layer of mesh. And then I submitted these pieces  
 25 for microscopic examination. I sent them to laboratory



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1 technicians to produce histological slides.  
 2 Q. Did you say pathological slides?  
 3 A. Histological slides.  
 4 Q. Histological slides, okay.  
 5 What does histology or histological slides, what does  
 6 that mean in your field?  
 7 A. Histological slides is when the tissue is examined in the  
 8 microscope.  
 9 Q. Did you prepare the slides from Ms. Bellew's explanted  
 10 mesh material in the same manner that you prepare pathology  
 11 slides in your normal daily practice?  
 12 A. Yes.  
 13 Q. Did you prepare the slides in a manner as a standard  
 14 pathologist would in your field or your industry?  
 15 A. Yes.  
 16 Q. Can you please explain the process of preparing pathology  
 17 slides for the jury as you did from Ms. Bellew's explant.  
 18 A. When the tissue is submitted to prepare the histological  
 19 slides, we need to take really thin sections so the light can  
 20 shine through and I can see it in the microscope. So we take  
 21 sections like sections of slices of the meat in the deli in  
 22 the grocery store. We take the sections and these thin  
 23 slices, then I put on glass slides, and you can see that. So  
 24 they are very thin, about five microns thick. Now the light  
 25 can shine through and I can see features inside the tissue.

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1 Q. How many slides did you prepare for Ms. Bellew's -- these  
 2 four explanted pieces?  
 3 A. 15.  
 4 Q. Are you prepared today to offer expert opinions and  
 5 conclusions for the Court and the jury based on your  
 6 pathological analysis of Ms. Bellew's explanted Prolift mesh  
 7 and tissue?  
 8 A. Yes.  
 9 Q. Will all of your opinions today be stated to a reasonable  
 10 degree of medical certainty?  
 11 A. Yes.  
 12 Q. Have you used your knowledge, training, experience as an  
 13 anatomical pathologist, as well as your review of her medical  
 14 records and these specimens in examining Ms. Bellew's  
 15 pathology and arriving at your opinions here in this case?  
 16 A. Yes.  
 17 Q. What methods did you use to analyze Ms. Bellew's  
 18 pathology specimens that you received in this case?  
 19 A. I used standard methods of staining and using polarizing  
 20 light.  
 21 Q. Okay. First of all, explain to the jury what staining  
 22 is.  
 23 A. Staining is using dyes, like for fabric, to dye tissue  
 24 because tissue is so thin, it's transparent. We cannot see  
 25 it. So first we need to stain it with dyes, and then we can

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1 see it in the microscopy.  
 2 There is also another role for stains. Some stain  
 3 stain on the specific structures so we can differentiate what  
 4 type of cells I'm looking at.  
 5 Q. Did you use any other standard methods in your industry  
 6 to analyze Ms. Bellew's explanted tissue to arrive at your  
 7 opinions today?  
 8 A. I used polarized light.  
 9 Q. Okay. Explain to the jury what polarized light on a  
 10 microscope means in term of analyzing explanted medical  
 11 devices or explanted mesh.  
 12 A. Polarized light, I need to use polarized filter. These  
 13 are like polarizing glasses. These glasses can be used for  
 14 fishing because when you look at water, the light shines,  
 15 there is too much light, and it's all in different directions.  
 16 You can see the surface of the water. But if you use  
 17 polarizing glasses, it's only one direction of light going  
 18 through the glasses, and you can see better if you caught the  
 19 fish. So the polarizing filters are like venetian blinds.  
 20 They let light in one orientation go through, like venetian  
 21 blinds.  
 22 So if we have two filters with the same orientation,  
 23 placed against each other, the light can go through. But if I  
 24 take this filter and I turn it, the orientation of filters is  
 25 perpendicular so the light cannot go through. But if there is

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1 object inside, between this filter, which can change  
 2 orientation, the light, which is perpendicular, turns through  
 3 the object and then passes through the next filter and I can  
 4 see it in the microscope.  
 5 Q. What is the application of that in this particular case,  
 6 and, that is, using polarized light microscopy to arrive at  
 7 any of your opinions here?  
 8 A. It was discovered about a hundred years ago and that  
 9 using this polarizing filters, we can see objects which are  
 10 clear or which are foreign, which are synthetic in the  
 11 microscopy, and it has been used since to identify foreign  
 12 objects in the histological slides.  
 13 Q. So did you use histological staining in the preparation  
 14 of slides as well as light microscopy with the polarized  
 15 lenses to examine Ms. Bellew's explants for which you are  
 16 going to offer opinions here today?  
 17 A. Yes.  
 18 Q. Okay. After you did the staining of her slides, what did  
 19 you do next?  
 20 A. I -- first of all, I need to see the history, analyze the  
 21 history. I have my differential diagnosis.  
 22 Q. When you say the history, what do you mean? Review the  
 23 medical records?  
 24 A. Yes.  
 25 Q. Okay. The medical records?

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1 A. Medical records, clinical history.  
 2 Then I examine the slides, stained with different  
 3 stains. And I could assess if there is mesh only and  
 4 mesh-related conditions or mesh-related changes in the tissue  
 5 or there is something else, natural, like a tumor or like a  
 6 vasculitis, something which would occur without the mesh. And  
 7 then I examined the polypropylene properties using polarizing  
 8 light.  
 9 Q. Did you take photographs of the slides while they were  
 10 under the microscope?  
 11 A. Yes.  
 12 Q. What's on the top of the microscope there?  
 13 A. This is a camera. I mean this is a standard Canon camera  
 14 to take pictures. I took pictures exactly the same way as you  
 15 take pictures.  
 16 Q. What is the purpose of taking photographs of the slides  
 17 while they're on the microscope?  
 18 A. To show it to other people and to document something.  
 19 Q. Did you bring Ms. Bellew's pathological slides that you  
 20 prepared here with you today?  
 21 A. Yes.  
 22 Q. Are they significant to your opinions in this case?  
 23 A. Yes.  
 24 Q. Did you rely upon them in forming your opinions in this  
 25 case?

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1 A. Yes.  
 2 MR. ANDERSON: Your Honor, could Dr. Iakovlev just  
 3 step down and show the jury the slides and the types of  
 4 staining that he did from his slide deck, if he agrees to  
 5 abide by the court rules of speaking up, facing the court  
 6 reporter, and continue to make it a Q and A with me?  
 7 THE COURT: Yes.  
 8 MR. ANDERSON: Thank you.  
 9 BY MR. ANDERSON:  
 10 Q. You may step down. Make sure your mic is still on.  
 11 A. So these are the 15 histological slides I prepared. And  
 12 you can see that they are different colors, red and green and  
 13 brown. The red color is H&E or hematoxylin and eosin stain,  
 14 we're using stains protein, and the pink color within is scar  
 15 tissue because it has a lot of protein, a lot of collagen.  
 16 This is trichrome stain, it uses green color to stain collagen  
 17 and you can see it's all green. And this brown stain, it  
 18 stains specific proteins, and I will show them later.  
 19 Q. What is the significance of -- back up just a little.  
 20 What is the significance of brown staining in those  
 21 particular photographs or photographic slides?  
 22 A. I could identify proteins such as S100, myeloperoxidase  
 23 and smooth muscle.  
 24 Q. And what is the significance of identifying S100,  
 25 myeloperoxidase in these slides?

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1 A. S100 stains nerves. I can see nerves easier with S100  
 2 stain. Myeloperoxidase is a chemical produced by macrophages  
 3 like immune cells which are coming in to fight this bacteria,  
 4 foreign bodies. So I can see if the macrophages, they are  
 5 functioning, they are expressing this chemical to destroy the  
 6 foreign body.  
 7 Q. Did you take photographs of her slides, Ms. Bellew's  
 8 slides while they were on the microscope?  
 9 A. Yes.  
 10 Q. And did you bring those photomicrographs with you today?  
 11 A. Yes.  
 12 Q. Okay. Why don't you put those down.  
 13 MR. ANDERSON: Your Honor, if I can --  
 14 THE COURT: May the witness resume the stand?  
 15 MR. ANDERSON: That's what I was going to ask you  
 16 about. He has taken photomicrographs and put them on the  
 17 boards for the jury. So if he would be allowed to stand in  
 18 front of the jury and show those, these are plaintiff's  
 19 Exhibit 1910, and they were included in his report and --  
 20 THE COURT: Did counsel see them?  
 21 MR. ANDERSON: Yes, sir.  
 22 THE COURT: Have you seen those?  
 23 MR. THOMAS: I have, Your Honor.  
 24 THE COURT: All right. Yes.  
 25 MR. ANDERSON: And --

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1 THE COURT: There are difficulties with the witness's  
 2 accent and it is helpful if he faces the court reporter so she  
 3 can see your mouth as you talk.  
 4 THE WITNESS: I will.  
 5 THE COURT: Thank you.  
 6 MR. ANDERSON: We worked this morning to try and --  
 7 THE COURT: Yes, Carol? Just a minute.  
 8 THE COURT REPORTER: If I could just move down there,  
 9 it would be better.  
 10 THE COURT: All right.  
 11 MR. THOMAS: Your Honor, can I move?  
 12 THE COURT: You absolutely may.  
 13 MR. THOMAS: Thank you, Your Honor.  
 14 BY MR. ANDERSON:  
 15 Q. Are these photomicrographs that you relied upon in  
 16 forming your opinions?  
 17 A. Yes.  
 18 Q. Are they significant to your opinions?  
 19 A. Yes.  
 20 MR. ANDERSON: Your Honor, we would seek to move 1910  
 21 into evidence, please.  
 22 THE COURT: It may be received.  
 23 MR. ANDERSON: Thank you.  
 24 MR. THOMAS: Your Honor?  
 25 THE COURT: Yes.

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1 MR. THOMAS: Some of the exhibits have writing on  
2 them. They are not the exact exhibits or the  
3 photomicrographs. Things have been added by him as  
4 descriptive. I don't think that's appropriate to be received  
5 into evidence.

6 THE COURT: All right. When we get to that, make  
7 that objection.

8 MR. ANDERSON: And I have a good solution for that,  
9 and that is like we have done with some of the PowerPoint  
10 slides, we will remove the slides that he has put wording on  
11 to be able to explain to the jury. Fair enough?

12 MR. THOMAS: That's fine with me.

13 THE COURT: Very well.

14 MR. ANDERSON: Thank you.

15 (PLAINTIFF EXHIBIT P-1910 WAS RECEIVED IN EVIDENCE.)

16 MR. THOMAS: May I sit over here, Your Honor?

17 THE COURT: Yes.

18 Otherwise, what are the numbers?

19 MR. ANDERSON: Yes, sir. So 1910-Z is what's on the  
20 left and 1910-Y is on the right.

21 BY MR. ANDERSON:

22 Q. What is significant about and why did you choose 1910-Z,  
23 Dr. Iakovlev?

24 A. This is a microphotograph of one of the pieces over here.  
25 So -- this is exactly from the slide and one of the pieces was

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1 unit.

2 Q. Do you have an opinion as to whether or not those layers  
3 were folded while they were still in Ms. Bellew's body?

4 A. Yes. Because as you can see, scar tissue fills  
5 completely the entire structure. This can happen only in the  
6 body while tissue can ingrow in all the spaces.

7 Q. Are you familiar with the term "fibrotic bridging"?

8 A. Yes.

9 Q. What does the term "fibrotic bridging" mean to you?

10 A. Fibrotic bridging is when scar tissue -- scar tissue is  
11 fibrous tissue -- bridges between filaments, and you can see  
12 the entire piece is fully encased in scar. This entire  
13 specimen is bridging.

14 Q. Are you familiar with the term "scar plates" and "scar  
15 encapsulation"?

16 A. Yes. Scar encapsulation is when something encapsulates  
17 the object, foreign object. In this case, you see scar  
18 tissues inside the foreign object and outside, encapsulating.  
19 And this complex of mesh as a rebar inside the scar is scar  
20 plated. This entire structure is scar plated.

21 Q. Are you familiar with the term "mesh contraction"?

22 A. Yes.

23 Q. Is there -- do you see mesh contraction in plaintiff's  
24 1910-Z?

25 A. So, as we heard this morning, the filaments themselves do

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1 photographed for these boards.

2 Q. And what is the jury seeing? What type of staining are  
3 we using -- did you use on the left-hand pathology slide?

4 A. As I mentioned, this is H&E, hematoxylin and eosin stain.  
5 It stains pink color collagen and inflammatory cells purple.

6 Q. What is the significance of the red or pink that we see  
7 in the -- in 1910-Z on the left?

8 A. Let me first orient the jurors what they see here. These  
9 clear spaces, these are polypropylene filaments because it's  
10 like fishing line, it's clear. We cannot see it when it's in  
11 the light microscope, it's transparent. But remember those  
12 blue threads in the gross specimen? Some of the threads in  
13 the Prolift device are colored blue, and you can see them blue  
14 here. See these colors? This blue, this blue, and this is  
15 blue.

16 Q. Is there anything significant about the orientation of  
17 the white and blue fibers as we see it in 1910-Z?

18 A. As you can see, that there is at least three layers of  
19 the mesh here. It helps it to identify where the mesh is  
20 going, and this yellow line shows layers of the mesh. There  
21 are three layers of the folded mesh within this piece, and, as  
22 I described, the red color represents collagen. So these  
23 three layers are all fused, glued together, cemented together  
24 by the scar tissue. It's like plywood. If you have several  
25 layers and then you glue them together, they become all as one

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1 not contract. What contracts is when the scar tissue grows  
2 in, it tends to contract. Our body developed this mechanism  
3 to minimize the damage.

4 You've probably seen in burn victims when there is  
5 scarring and then it contracts the joint, it cannot move. The  
6 scar tries to pull together, become smaller.

7 The same thing happens here. When the scar tissue  
8 grows in, it contracts. This is physiological. This happens  
9 to any scar tissue, contracts and pulls everything together.  
10 And you can see that there is this wrinkling which occurred in  
11 the body because it's completely fused by the scar tissue.

12 Q. Do you have an opinion to a reasonable degree of medical  
13 certainty as to what part of Ms. Bellew's body this explanted  
14 piece came from? Do you have an opinion?

15 A. Yes.

16 Q. And what is that opinion?

17 A. My opinion is that it came from the anterior vaginal  
18 wall, from between the vagina and the bladder, and from this  
19 corner, I can see neuroganglia and nerves.

20 Q. Okay. Let's talk about that term real quickly because  
21 it's important. What is neuroganglia?

22 A. Neuroganglia are part of involuntary nerve system which  
23 controls blood. We know that all nerves come from the outside  
24 into the midline. So they come towards the midline, towards  
25 the vagina and the bladder. So I know that this part is

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1 further to the outside, towards the arm of the device, the  
 2 Prolift device, and this part would be closer to the  
 3 midportion, where you have enough mesh to fold into this  
 4 folded structure.  
 5 Q. Is there anything else significant about the orientation  
 6 of the fibers on plaintiff's Exhibit 1910-Z? Near the  
 7 neuroganglia, is there anything significant about the top  
 8 portion where you were just referring to?  
 9 A. So, when you have a large device, large sheet, it folds.  
 10 But when you have just an inch, it curls. So this curling, if  
 11 it is a narrow arm of tape, occurs on both sides. So this  
 12 curling on both sides is like a rolling or roping. This is  
 13 called roping because it forms this round structure.  
 14 Q. And do you see that depicted in 1910-Z?  
 15 A. (Indicating.)  
 16 Q. Indicating to the top of the board?  
 17 A. Yes.  
 18 Q. Just for the record.  
 19 A. Yes, in this part. This is an edge which is curled. So  
 20 this part would be called roping. So the edge is roped like  
 21 this. (Indicating.)  
 22 Q. In your opinion, Doctor, what degree of scarring is shown  
 23 in the explanted tissue in 1910-Z?  
 24 A. As I said, this is all scar tissue. This is as hard as  
 25 it gets. I mean, there is no non-scar tissue in this

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1 specimen.  
 2 Q. And that's the next question. Is there any healthy  
 3 tissue that you can see in plaintiff's 1910-Z in and around  
 4 the fibers of that explant?  
 5 A. Not around the fibers. There is a little corner here,  
 6 transition, but the mesh was excised right at the scar.  
 7 Q. Okay. Now, anything else significant about those before  
 8 we move on to the next board?  
 9 A. No.  
 10 Q. Okay. Let's look at 1910-NN and MM.  
 11 First of all, Dr. Iakovlev, let's explain what the jury  
 12 is seeing on their left in plaintiff's 1910-NN.  
 13 A. This is a high magnification of the same section you saw  
 14 before. I've zoomed in and took high magnification photograph  
 15 of the mesh filaments and surrounding tissue.  
 16 Q. Why did you do that?  
 17 A. To show the changes close up and to help you to identify  
 18 where the mesh filaments are, because they're clearer. I  
 19 filled them with yellow color on this. This is exactly the  
 20 same image but just a copy with yellow color representing mesh  
 21 filaments.  
 22 Q. And you have on there foreign body and lymphoplasmacytic  
 23 chronic inflammation. Let's just go with chronic inflammation  
 24 in the foreign body part. Why do you have those on the board  
 25 to the right, 1910-MM?

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1 A. As I mentioned before, any foreign body placed in the  
 2 body or which occurs in the body is recognized by the immune  
 3 system by the body as foreign. So the body sends white blood  
 4 cells or macrophages to fight with it, to destroy it. So the  
 5 foreign body reaction is an immune response and the body sends  
 6 fighter cells to express all those chemicals, reactive  
 7 chemicals, to destroy either bacteria or foreign body.  
 8 Q. Now, what is the relationship between a foreign body  
 9 reaction and foreign body inflammation?  
 10 A. It's the same, inflammation, reaction is the same.  
 11 Q. And, again, in these photomicrographs, do you see any  
 12 evidence of the chronic foreign body reaction as well as  
 13 chronic inflammation?  
 14 A. Yes. Sometimes these terms are used interchangeably.  
 15 Chronic foreign body reaction includes macrophages which are  
 16 large cells. They look kind of purple. Also, when they come  
 17 to the object and they feel that they cannot destroy it as one  
 18 by one, they try to merge together and form a large  
 19 multinucleated cell, so because the large cells can absorb  
 20 larger objects and you can see it here. This is a  
 21 multinucleated giant cell. This is multinucleated giant cell.  
 22 This is multinucleated cell. There are multiple nuclei. This  
 23 is the same macrophage but it's like a battalion of them  
 24 joined together in an effort to destroy the foreign body.  
 25 Q. Is the inflammation that we see in 1910-NM [sic], is any

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1 of that inflammation transient or temporary?  
 2 A. Absolutely not. The foreign body reaction will stay in  
 3 the body as long as foreign body stays in the body, until the  
 4 foreign body is either destroyed or removed.  
 5 Q. Do you have an opinion to a reasonable degree of medical  
 6 certainty, based upon your knowledge, training and experience,  
 7 all the medical records you reviewed in this case, the  
 8 specimens you reviewed, and the specimens that you reviewed as  
 9 a pathologist at St. Michael's, as to whether or not  
 10 Ms. Bellew's Prolift mesh caused the chronic foreign body  
 11 reaction and chronic inflammation that we see in plaintiff's  
 12 Exhibit 1910-NM -- NN?  
 13 A. Yes.  
 14 Q. And what is that opinion?  
 15 A. My opinion is that the mesh placed in Ms. Bellew's body  
 16 caused this foreign body reaction.  
 17 Q. Did it cause a chronic inflammation?  
 18 A. Yes, it caused chronic inflammation.  
 19 Q. Did you rule out other causes of the chronic  
 20 inflammation, the chronic foreign body reaction, and any other  
 21 condition that could cause -- well, first of all, let me go  
 22 back a minute.  
 23 What is the structure on the top right?  
 24 A. This is a nerve.  
 25 Q. Okay.

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1 A. So this nerve goes around the filament, and you can see  
 2 it's pinched here between the scar tissue and mesh filament.  
 3 Also, seeing a nerve in the tissue means that the tissue can  
 4 sense pain because without the nerves, it would feel nothing.  
 5 Q. You've heard the term "pinched nerve" in medicine. Is  
 6 that what we have in 1910-NN?  
 7 A. You can see the shape of the nerve, how it is all  
 8 squished here.  
 9 Q. What's the result to a patient of a pinched nerve in the  
 10 tissue surrounded by scar tissue?  
 11 A. It would cause pain.  
 12 Q. Do you have an opinion to a reasonable degree of medical  
 13 certainty as to whether this nerve that is pinched in  
 14 plaintiff's 1910-NN caused pain in Ms. Bellew?  
 15 A. Yes.  
 16 Q. And what is that opinion?  
 17 A. My opinion is that this deformation is likely to cause  
 18 pain.  
 19 Q. As part of your coming to your expert conclusions, did  
 20 you rule out any other causes of the chronic foreign body  
 21 reaction, the chronic inflammation, or the pinched nerve as we  
 22 are seeing in these photos?  
 23 A. Yes.  
 24 Q. What did you do to rule out other causes?  
 25 A. Well, when I examined the specimen, I considered all

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1 possibilities --  
 2 Q. Talk a little bit slower if you could, please.  
 3 A. I considered all possibilities. Is there a natural  
 4 condition which could cause all these changes, is there  
 5 another foreign body which could cause all these changes, and  
 6 I did not see anything. I saw just Prolift mesh and tissue  
 7 reaction to it.  
 8 Q. Did you rule out any other disease conditions?  
 9 A. Yes. I didn't see, as I mentioned, vasculitis, cancer,  
 10 or any other systemic conditions.  
 11 Q. Okay. Now, anything else before we leave these?  
 12 A. Well, since we were talking about nerves, I wanted to  
 13 approach how we could sense pain. There are two ways of  
 14 sensing pain.  
 15 Q. Okay. What are those?  
 16 A. Either we have pinched nerve, nerve itself, or we feel  
 17 pain through receptors, the receptors are irritated. We have  
 18 pain receptors but we also have other receptors like  
 19 temperature or vibration. Pain receptors, they send signals  
 20 of pain only. Other receptors, they can send different  
 21 signals. Like for temperature, when we feel warm, we feel  
 22 warm, but when there is too much heat, we feel it as pain, as  
 23 burning pain. So if the receptors are very much irritated, we  
 24 can feel it as pain.  
 25 Now, in the inflamed area, the receptor sensitivity

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1 goes up, they become sensitive. It's like a pimple or like an  
 2 inflamed area. It may not hurt if we don't touch it or move  
 3 it, but the receptors are sensitized already. Once we touch  
 4 it or move it, we feel pain. And if there is a lot of  
 5 inflammation, we can feel pain at rest, it hurts. An inflamed  
 6 knee can hurt or inflamed wound can hurt.  
 7 Q. Do you have an opinion, Doctor, as to whether or not the  
 8 inflamed area around -- first of all, did you see these  
 9 inflamed areas in other pathological specimens that you looked  
 10 at from Ms. Bellew?  
 11 A. This inflammation was surrounding all filaments. The  
 12 entire mesh area was an inflamed area. So it wasn't just this  
 13 small area. You can imagine the device, and the entire device  
 14 is inflamed. It's a large area of inflammation.  
 15 Q. Okay. Do you have any other slides with you regarding  
 16 nerve damage or nerve entrapment for Ms. Bellew?  
 17 A. Yes.  
 18 Q. Okay. I think those are 1910-BBB and 1910-AAA.  
 19 You talked to the jury a little earlier about the  
 20 different types of staining. I think you said the first one  
 21 was H&E; is that correct?  
 22 A. Yes.  
 23 Q. And what is the staining that they see here?  
 24 A. This is the brown stain, and I ordered my lab to do S100  
 25 stain. S100 stain stains nerves. I could see and show nerves

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1 easier with this stain.  
 2 Q. Okay. Let's look at the BBB there, 1910-BBB, and explain  
 3 what you're talking about to the jury.  
 4 A. So, as before, the clear spaces are spaces of the  
 5 filaments of the Prolift device, removed from Ms. Bellew's  
 6 body. In this image, it's the same image, a copy. The empty  
 7 spaces of polypropylene filaments are filled yellow and the  
 8 brown color shows nerves in the tissue.  
 9 Q. What is the significance of findings of the nerves in  
 10 this as it relates to any clinical pathological correlation  
 11 with Ms. Bellew's pain symptoms?  
 12 A. Well, first of all, just by orientation.  
 13 Q. By orientation, did you say?  
 14 A. Orientation.  
 15 Q. Okay.  
 16 A. And then the nerves, I can identify that this part of the  
 17 nerve was further away from the midline, from the center.  
 18 Because, as I explained before, the nerves are coming from  
 19 outside into inside, so they come out like this and then they  
 20 go and innervate the vagina and the bladder. So this piece of  
 21 mesh was oriented like this, in more lateral or further  
 22 outside position. This part was consistent with arm of the  
 23 Prolift device. And you can see that there are a number of  
 24 nerves in this arm of the Prolift device. Some of them are  
 25 straight.



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1 Q. Is that a normal appearance, as long as they're straight?  
 2 A. Yes, this would be normal appearance. And some of them  
 3 are bent, and some of them are severely distorted by the  
 4 Prolift mesh filaments.  
 5 Q. Explain what you mean by that.  
 6 A. It would be easier if I showed the blowup and  
 7 magnification of this area.  
 8 Q. Okay. Is that 1910-ZZ? Yes.  
 9 A. Yes. 1910-ZZ and --  
 10 Q. 1910-L?  
 11 A. L.  
 12 Q. Okay.  
 13 A. So 1910-ZZ is magnification of an area. 1910-BBB,  
 14 high-powered view.  
 15 Q. Explain what the jury is seeing there.  
 16 A. This end of the nerve, the nerve fibers are oriented  
 17 here, and now we can see that the nerve fibers are indicated  
 18 here as perpendicular.  
 19 Q. Is that the area that looks like a fist?  
 20 A. Yes.  
 21 Q. Okay. Explain what that is, please.  
 22 A. The mesh -- the nerve is distorted by the mesh and it  
 23 forms this bulbous enlargement and changed the course  
 24 orientation, and then further down, this nerve is more  
 25 severely distorted, and the fascicles, the particles inside of

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1 all of these specimens that you looked at that we saw grossly  
 2 on the screen and that now we're looking at microscopically  
 3 were removed during that July, 2012, explant in an area where  
 4 Ms. Bellew had complained of pain? Do you have an opinion on  
 5 that?  
 6 A. Yes.  
 7 Q. And what is it?  
 8 A. It corresponds --  
 9 Q. Sorry.  
 10 A. Yes. It corresponds to the location of the pain, the  
 11 description of the scarred firm mesh, and I concur with the  
 12 clinical symptoms, with the morphological findings.  
 13 Q. You said morphological? Explain what morphological  
 14 findings are, please.  
 15 A. Morphology is the science of anatomy and histology, is  
 16 what it is, using microscope and gross appearance.  
 17 Q. Okay. Go ahead.  
 18 A. And I found multiple deformations of the nerves, forming  
 19 traumatic neuromas, excising all the particles of the specimen  
 20 and I can measure that. There can be more of these lesions in  
 21 the remaining mesh.  
 22 Q. Okay. Now, if we could, let's look at plaintiff's  
 23 Exhibit 1910-KKK and 1910-CC.  
 24 And, first of all, let's explain to the jury, after you  
 25 get that one up there, what they're seeing in 1910-KKK.

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1 the nerve, are being separated in the scar tissue.  
 2 Q. What is the significance to a patient when the fascicles  
 3 of the nerve have been separated like they are here around the  
 4 mesh fiber?  
 5 A. This is a pathological process which forms traumatic  
 6 neuroma.  
 7 Q. What is traumatic neuroma?  
 8 A. Traumatic neuromas form when the nerve is distorted or  
 9 when it continues to grow in the scar tissue and it hits an  
 10 obstacle, it cannot grow further, and what happens when it  
 11 hits the obstacle, the fascicles separate, and then they kink  
 12 together and then it forms this bulbous enlargement like a  
 13 pseudotumor.  
 14 Q. In your opinion, what was the clinical impact on patient  
 15 safety to Ms. Bellew with regard to these distorted nerves and  
 16 the separated fascicles that we see in 1910-ZZ?  
 17 A. It's well established that traumatic neuromas are  
 18 severely painful lesions. And it wasn't just one. I found  
 19 several traumatic neuromas in the specimens I removed from  
 20 Ms. Bellew.  
 21 This is another one, and you can see it has even more  
 22 severe inflammation, separation of the fascicles, and the  
 23 fascicles are all in scar tissue, and this is the larger side  
 24 of the nerve which is distorted and forms traumatic neuroma.  
 25 Q. And, again, do you have an opinion as to whether or not

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1 A. This image, it's the same brown type of staining, but I  
 2 ordered my lab to do smooth muscle stain. It stains smooth  
 3 muscle of bladder wall, the muscle which contracts during  
 4 urination.  
 5 And in this image I filled polypropylene filaments with  
 6 yellow color so you can orient. All this tissue is scar  
 7 tissue.  
 8 Q. Is that the light brown area in between the yellow that  
 9 you're referring to?  
 10 A. Yes. There is some areas which are brown. It's blood  
 11 vessels in the scar tissue because they also have smooth  
 12 muscle inside the vascular wall.  
 13 Q. So if this was an H&E staining, this hematoxylin and  
 14 eosin, what would the light brown color stain, what color  
 15 would it stain?  
 16 A. This would be all pink. The entire area would be pink.  
 17 Q. Okay. Now, you have these thick bundles of smooth  
 18 muscle. Explain to the jury what you're referring to there  
 19 and how it relates to the mesh.  
 20 A. So to see smooth muscle, I ordered smooth muscle stain,  
 21 and you can see sharp distinction. This part was scar, and  
 22 this part was smooth muscle of the bladder.  
 23 Q. Explain to the jury the -- what smooth muscle is in terms  
 24 of our body.  
 25 A. Smooth muscle is muscle inside our organs like bowel,

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1 contract bowel, like bladder, when it contracts, we urinate,  
 2 so this is muscle of the bladder.  
 3 Q. So you're pointing to 1910-KKK. Do you have an opinion  
 4 as to whether or not this specimen shows Ms. Bellew's mesh up  
 5 against the detrusor muscle or the smooth muscle of her  
 6 bladder?  
 7 A. Yes.  
 8 Q. Do you have an opinion as to whether or not in 1910-KKK,  
 9 it represents pathological findings that would be consistent  
 10 with any urinary symptoms?  
 11 A. Yes.  
 12 Q. And what is that opinion?  
 13 A. My opinion is that the scar tissue and the mesh were  
 14 interfering with the smooth muscle of the bladder.  
 15 Q. And what are we seeing in 1910-CC?  
 16 A. This is H&E stain, hematoxylin and eosin, as before.  
 17 This is a blow-up picture of that corner of the -- of the  
 18 Exhibit Z. This is this area, enlargement. As I mentioned  
 19 before, it contains neuroganglion. Ganglia is like a center  
 20 where nerves of the involuntary nervous system connect. This  
 21 is the ganglia. So if I see the ganglia, I know that the  
 22 nerves, which are connecting to it, are going into the  
 23 bladder. So if we look between the vagina and the bladder,  
 24 some nerves go into the vagina and they innervate the vagina.  
 25 Q. What do you mean by innervate? What does that term mean?

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1 A. They shoot their endings into the vagina so the vagina  
 2 can feel and the muscle of the vagina can contract.  
 3 Q. Okay. Go ahead, please.  
 4 A. And then other nerves which are connecting through the  
 5 neuroganglia, they go into the bladder, and we feel urge to  
 6 urinate through work of these ganglia and nerves, and we also  
 7 urinate, the bladder contracts, through work of these ganglia  
 8 and nerves.  
 9 Q. Anything else significant about these that you wanted to  
 10 share with the jury?  
 11 A. You can see that these nerves are also deformed. There  
 12 are four. The mesh was interfering with bladder innervation.  
 13 It was interfering with the nerves which were going into the  
 14 bladder.  
 15 Q. In addition to causing urinary problems for the patient,  
 16 would -- to your opinion, would the scar tissue that we see in  
 17 CC surrounding the nerve have any implications for  
 18 Ms. Bellew's condition?  
 19 A. Yes. Because, as we mentioned before, scar tissue adds  
 20 stiffness and hardness of the folded mesh.  
 21 The second significance is that scar tissue entraps  
 22 nerves and pinches them. So the nerves here are entrapped and  
 23 pinched between scar tissue and the mesh filaments.  
 24 Q. Can that cause chronic pelvic pain in patients?  
 25 A. Yes.

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1 Q. Do you have an opinion as to whether or not the  
 2 entrapment of the nerves that you've seen and the pathological  
 3 symptoms here were caused by the Prolift mesh?  
 4 A. Yes.  
 5 Q. Do you have an opinion as to whether or not the Prolift  
 6 mesh caused chronic pain for Ms. Bellew?  
 7 A. Yes.  
 8 Q. And what is that opinion?  
 9 A. My opinion is that mesh -- Prolift mesh device and tissue  
 10 reaction to it caused pain for Ms. Bellew.  
 11 Q. Do you have an opinion as to whether or not the Prolift  
 12 mesh caused chronic dyspareunia or sexual problems and sexual  
 13 pain for Ms. Bellew?  
 14 A. Yes, I have opinion. This pain --  
 15 Q. Go ahead. What's that opinion?  
 16 A. This pain symptoms, dyspareunia, has the same basis,  
 17 because it's the same pain, with external mechanical stimuli,  
 18 so the mesh and tissue reaction to mesh caused dyspareunia for  
 19 Ms. Bellew.  
 20 Q. And do you have an opinion to a reasonable degree of  
 21 medical certainty as to whether or not the pathological  
 22 analysis you've done have shown that Ms. Bellew's urinary  
 23 symptoms are due -- urinary problems are due to Prolift?  
 24 A. My pathological findings show that there was interference  
 25 with urinary function.

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1 Q. And as to the specific problems that this scar tissue  
 2 would have caused to her urinary symptoms, do you have an  
 3 opinion on that or would you defer to a urologist?  
 4 A. Specifically what was the urinary symptoms? I would have  
 5 to defer to urologist.  
 6 Q. Okay. Ready to take those down?  
 7 Okay. Doctor, handing you what has been marked as  
 8 plaintiff's Exhibits P-1910-G and P-1910-M. Please explain to  
 9 the jury what we're seeing in these two images.  
 10 A. These are very high magnification images of polypropylene  
 11 filaments. When the filaments are cut like salami, we look at  
 12 them from the cut surface. If you imagine salami and then  
 13 it's cut, so this is the filament, very high magnification,  
 14 about a thousand times magnification. As I mentioned before,  
 15 polypropylene is like fishing line, it's clear, so in the  
 16 microscope, it appears clear, we do not see it. And the  
 17 tissue around it --  
 18 Q. What are we seeing, the pink and the purple there in the  
 19 tissue around the polypropylene fiber?  
 20 A. This is chronic foreign-body-type inflammation  
 21 surrounding the filament.  
 22 Q. And what is this -- out where you have a line going to  
 23 the degradation bark, explain what you're trying to show the  
 24 jury there, please.  
 25 A. If you allow me to --

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1 Q. Sure.

2 A. -- take another exhibit.

3 Q. Sure.

4 A. I brought this slice of wood which was cut with a chain  
5 saw just to explain some things.

6 So the mesh filament is like a tree trunk. And when we  
7 section it, now we're looking at the section like this. So  
8 the core of the wood is homogenous, solid like the core of the  
9 filament, but then there is a bark tree [sic] around the tree  
10 trunk.

11 Q. What is the significance of that cracked outer layer that  
12 we're seeing in 1910-G?

13 A. This is the bark layer or outer layer of the degraded  
14 polypropylene. It's the same wood but because it was exposed  
15 to the outside environment, it's all cracked. It has all  
16 these crevices, cracks, and cavities. The same thing happens  
17 with the polypropylene. When it's exposed to the body  
18 environment, it cracks and forms these cavities, and the  
19 histological dye, it gets trapped in it so it sticks in  
20 between. It's like clothing. The dye gets in between the  
21 fibers in the clothing and that's why it stains. The  
22 non-degraded polypropylene is solid, so it cannot be stained.

23 Q. What is the significance to the patient in terms of the  
24 tissue reaction in and around the degraded bark as we're  
25 seeing in 1910-G?

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1 A. So, the tissue reaction, as we discussed before, is  
2 designed to destroy foreign bodies. So all these macrophages,  
3 they produce chemicals to oxidize, to destroy foreign body.  
4 That's what happens. Polypropylene oxidizes and degrades in  
5 the body. Then --

6 Q. What is the impact to the patient as a result of this  
7 degrading of the polypropylene in the body?

8 A. As you can see, the bark peeled off here, it cracked  
9 here, while the central core didn't crack. So the outer --  
10 the outer bark became brittle, hardened. We know that if the  
11 material is flexible, it would flex. If the material is  
12 harder, it will crack. You just bend it more, it will crack.  
13 And without bending, when it dries up inside, when there is  
14 force inside, it pulls it and it cracks. It's like dry lips  
15 or something which is drying and it cracks. It -- it has  
16 cracks on the surface. So this is continuous tube-like  
17 sheaths around all filaments in the mesh. And this is a tube  
18 which is hardened, and the entire mesh becomes stiffer and  
19 harder.

20 Q. Do you have an opinion as to whether or not the Prolift  
21 mesh that was implanted in Ms. Dianne Bellew degraded?

22 A. Yes.

23 Q. And what is that opinion?

24 A. My opinion is that the polypropylene of the Prolift  
25 device degraded while in the body of Ms. Bellew.

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1 Q. Do you have an opinion as to whether or not the degraded  
2 polypropylene in Ms. Bellew caused an increased inflammatory  
3 response?

4 A. Yes.

5 Q. What is that opinion?

6 A. We all know that if a material doesn't degrade, like  
7 high-quality stainless steel hips, there is no degradation,  
8 and then the inflammatory reaction goes away. No degradation,  
9 no reaction. When there is degradation, it's like a feeding  
10 frenzy. There are pieces which go into the tissue and they  
11 feed this inflammatory reaction. It's like birds, when you  
12 feed them, more and more come.

13 Q. What is the jury seeing in 1910-M that you put up here?

14 A. This is the polarization technique. This is exactly the  
15 same filament.

16 Q. Did you say polarization?

17 A. Polarization.

18 Q. Is that those lenses you were talking about when you go  
19 fishing?

20 A. Yes.

21 Q. Okay. Tell us about that.

22 A. So, to take this photograph, I turned polarizing filter  
23 and the light was blocked. This light of this area is dark.  
24 Because tissue doesn't polarize much of the light, it doesn't  
25 change orientation. If it's blocked, it's blocked. However,

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1 polypropylene changes orientation.

2 Q. Changes the orientation of the light?

3 A. Of the light.

4 Q. Okay.

5 A. It's called polarization. So the light goes through the  
6 filter, hits polypropylene, changes orientation, and then  
7 processes through the second filter.

8 Q. So fiberoptic technology, is that where light is passing  
9 through something like polypropylene?

10 A. Yes.

11 Q. Is it the same idea?

12 A. Yes.

13 Q. Okay. Doctor, what did you do to rule out whether or not  
14 there was something else that may have caused the cracking  
15 around the degraded core? Let me ask it a little bit  
16 differently.

17 Did you do anything to rule out whether or not this  
18 cracking, cracked outer layer, was something other than  
19 polypropylene associated with the fiber?

20 A. Yes.

21 Q. Okay. What did you do to rule out that it was something  
22 else other than polypropylene that we're seeing here?

23 A. First of all, I used polarization because this is  
24 standard technique, we use polarization --

25 Q. When you say "we," are you talking about pathologists use

Page 665

1 it?

2 A. Pathologists.

3 Q. Okay. Go ahead.

4 A. If it lights up, it's foreign body or crystals.

5 As you can see here, all tissue around is dark. There

6 is very little light going through collagen. Collagen is the

7 strongest polarizing protein in the body. When the entire

8 tissue is fixed in formalin, it's cross-linked in formalin,

9 and this is as bright as it gets for all human proteins fixed

10 in formalin. And you can see the difference between

11 polypropylene and the strongest polarizing protein fixed in

12 formalin.

13 Q. Do you have an opinion as to whether or not the

14 degraded -- what you have depicted as degraded polypropylene,

15 this cracked outer layer, is biologic material like protein or

16 polypropylene?

17 A. Yes, I do.

18 Q. What is that opinion?

19 A. It is not biologic polypropylene -- it's not biologic

20 material. It is synthetic polypropylene.

21 Q. Did you do anything to rule out whether or not the

22 formalin that Ms. Bellew's explant samples came in had

23 anything at all to do with the degradation bark in the cracked

24 outer layer?

25 A. Yes, I did.

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1 Q. What did you do?

2 A. I took new slices, I put them in formalin, kept them in

3 formalin for up to four months, and then loaded them in the

4 same machine, with the same samples, St. Michael's Hospital, I

5 went through all those chemicals, and then through the same

6 staining, and I did not see degradation of polypropylene after

7 four months of fixation in formalin, and the same process and

8 chemicals and temperature changes.

9 Q. Did you use operating procedures that are standard in

10 your industry to conduct this formalin testing on pristine

11 mesh that had never been implanted in a body?

12 A. Yes, they were loaded exactly with the same specimens.

13 Q. And are those standard operating procedures used at your

14 hospital at St. Michael's and the University of Toronto?

15 A. Yes.

16 Q. Now, what else do you have there? Do you have another

17 slide or two and then we can finish up here?

18 This is 1910-P. Please tell the jury what we're seeing

19 in 1910-P.

20 A. As you remember, those blue threads I showed on gross

21 photograph, and also on histological images, these blue

22 threads are manufactured with additional blue dye. When we go

23 to really high magnification, this blue -- this blue dye looks

24 like blue granules.

25 Q. And that's the blue fibers that we see running through --

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1 the jury has seen the Prolift mesh. Those would be those blue

2 fibers?

3 A. Yes.

4 Q. Okay.

5 A. So this is cross-section of clear filament. And this is

6 cross-section of blue filament. So since the granules were

7 embedded during manufacturing in polypropylene, they are like

8 internal markers of polypropylene. You can see granules here

9 in the filament. You can see granules --

10 Q. Why is that significant to your opinions with regard to

11 degradation and the outer layer being polypropylene?

12 A. It is significant because this is internal marker. If I

13 see blue granules, it means it's polypropylene which was

14 manufactured, even before it was implanted in the body. I did

15 not see blue granules beyond the surface. They were in the

16 non-degraded core of the filaments, they were present in the

17 degraded bark, they were mainly present deeper inside, and

18 then they degrade towards the surface, and they were not

19 present in the tissue.

20 Q. Okay. All right. Before we -- before we sit down,

21 plaintiff's Exhibit 1910-CC, is that -- where you put some

22 arrows and yellow spots, just for the record purposes, is that

23 the same image that is in plaintiff's Exhibit 1910-EE?

24 A. Yes.

25 Q. Okay. Thank you.

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1 Now, I think you can resume the stand now, Doctor.

2 Anything more about this image?

3 A. No.

4 Q. Okay. I see you brought your microscope with you.

5 THE COURT: Wait just a second.

6 MR. ANDERSON: Yes, sir. I'm sorry.

7 THE COURT: Go ahead, Mr. Anderson.

8 MR. ANDERSON: Sorry. Thank you, Judge.

9 BY MR. ANDERSON:

10 Q. I see you brought your microscope with you today. You

11 had been talking about this polarized light microscopy. Are

12 you prepared to at least show the jury one example of that on

13 one slide before we are through here today?

14 A. (Nods head.)

15 Q. Okay. Did you bring something with you to show them?

16 A. Yes, I brought those slides.

17 Q. Okay. May I approach, Your Honor?

18 THE COURT: You may.

19 MR. ANDERSON: Thank you.

20 BY MR. ANDERSON:

21 Q. What is the jury seeing -- I will let you get oriented.

22 Let me know when you're ready.

23 A. So, this is the same slide I showed you before, the slide

24 I took pictures of for the boards. And now I put live slide

25 in the microscope and I am projecting image from this camera.

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1 Q. Okay. And so you were saying that you wanted to use  
2 light microscopy. Are those the lenses that you have in your  
3 hand?  
4 A. Yes. This is one lens.  
5 Q. Okay.  
6 A. And one lens is in between the camera and the object  
7 here.  
8 Q. Please demonstrate what the significance would be of  
9 using the polarized images for -- in order to identify foreign  
10 material.  
11 A. So I'm going to place this filter in the microscope, and  
12 you can see that all tissue goes dark. Polypropylene --  
13 Q. What are the light spots that we're seeing?  
14 A. This is polypropylene.  
15 Q. So is that light being projected down through the image  
16 and bending through the polypropylene?  
17 A. Yes.  
18 Q. And what's all the black area?  
19 A. This is all tissue, human tissue, fixed in formalin.  
20 Q. Why is that significant to your opinions in this case, if  
21 at all?  
22 A. That's how I identify what is polypropylene and what is  
23 human tissue.  
24 Q. Okay. You can shut that down.  
25 Now, Doctor, with my help, did we prepare a slide today

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1 Q. Can you list those clinical symptoms, please?  
2 A. Chronic pelvic pain, chronic painful sexual intercourse  
3 which is dyspareunia, and change of urinary symptoms.  
4 Q. Okay.  
5 MR. ANDERSON: That's all I have for the direct, Your  
6 Honor.  
7 THE COURT: All right. That makes a good time for us  
8 to take a morning break before cross-examination.  
9 Ladies and gentlemen, during the break, do not  
10 discuss the case among yourselves or permit anyone to discuss  
11 it with you. Don't use any social or digital media for any  
12 purpose about this case. I'll call you back in 15 minutes.  
13 The witness may step down. Please don't talk to  
14 anybody during the break. All right.  
15 THE OFFICER: All rise.  
16 (The Jury left the courtroom at 10:34 a.m.)  
17 (A recess was taken at 10:34 a.m.)  
18 (The jury entered the courtroom at 10:52 a.m.)  
19 THE COURT: Thank you, ladies and gentlemen.  
20 If the witness would retake the stand,  
21 cross-examination is now in order.  
22 MR. THOMAS: Thank you, Your Honor.  
23 (CROSS EXAMINATION OF VLADIMIR IAKOVLEV BY MR. THOMAS:)  
24 Q. Hello, Doctor.  
25 A. Hi.

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1 regarding your clinicopathological findings as they relate to  
2 your opinions related to Ms. Bellew?  
3 A. Yes.  
4 THE COURT: All right. You may proceed.  
5 MR. ANDERSON: Thank you.  
6 BY MR. ANDERSON:  
7 Q. So, I want to go through these clinicopathological  
8 findings real quickly if I could, Doctor.  
9 You see there mesh folding and roping, scar  
10 encapsulation, scar plate, fibrotic bridging, mesh  
11 contraction, chronic foreign body inflammation, nerve  
12 entrapment and deformation, traumatic neuroma, and degradation  
13 of polypropylene fibers.  
14 Do you have an opinion to a reasonable degree of  
15 medical certainty based upon your knowledge, training and  
16 experience, your work as a pathologist for 15 years, your work  
17 on this case reviewing the medical records of Dianne Bellew,  
18 your work reviewing the explanted specimens from Dianne  
19 Bellew, as to whether or not all of these clinicopathological  
20 findings occurred in Ms. Bellew?  
21 A. Yes.  
22 Q. What's that opinion?  
23 A. My opinion is that all these morphological changes were  
24 related to mesh placement in the body and body reaction to it.  
25 And these changes caused these clinical symptoms.

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1 Q. As a part of your work in this case you've not examined  
2 Mrs. Bellew; correct?  
3 A. Yes, that's correct.  
4 Q. And you've not talked to Ms. Bellew about the case?  
5 A. That's correct.  
6 Q. And you've not talked to any of her treating physicians;  
7 correct?  
8 A. That is correct.  
9 Q. And not reviewed any of their depositions. Am I right?  
10 A. That's correct.  
11 Q. And you have no opinion in this case about whether the  
12 surgeon placed the Prolift properly at the time of the July,  
13 2009, implant; correct?  
14 A. I don't have an opinion.  
15 Q. You know the implant date was July 9, 2009?  
16 A. Yes.  
17 Q. And you know that the explant date of the mesh that you  
18 analyzed was July 12, 2012?  
19 A. That's correct.  
20 Q. So, the mesh that you looked at was in Ms. Bellew for  
21 about three years; correct?  
22 A. That's correct.  
23 Q. And at the time of the explant surgery, the surgeons sent  
24 the explants that you reviewed to the hospital pathology  
25 department, didn't they?



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1 A. That's correct.  
 2 MR. THOMAS: Your Honor, may I approach?  
 3 THE COURT: You may.  
 4 BY MR. THOMAS:  
 5 Q. Doctor, I've handed you what's been marked as  
 6 Defendant's Exhibit 10041. And you recognize this as  
 7 the surgical pathology report for Northwest Medical  
 8 Center which is the pathology department that received  
 9 Ms. Bellew's mesh following her surgery?  
 10 A. That's correct.  
 11 Q. And the pathologists at the Northwest Medical Center did  
 12 not conduct the same kind of analysis that you did, did they?  
 13 A. You're correct. They received, documented, and sent the  
 14 specimen to Steelgate.  
 15 Q. At least at that time, the pathologist didn't think it  
 16 necessary to make slides and analyze them for the purposes  
 17 that you did. Fair?  
 18 A. I don't know.  
 19 Q. But you haven't seen any pathology report analyzing  
 20 Ms. Bellew's slides beyond what you've done, have you?  
 21 A. Could you repeat the question?  
 22 Q. Sure. Have you seen a report from the pathologist at the  
 23 Northwest Medical Center analyzing this mesh in the same  
 24 manner that you did?  
 25 A. As I stated, this is the report and they received,

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1 removed?  
 2 A. Yes, I do.  
 3 Q. And you know three of those pieces were sent to an  
 4 analytical chemist to analyze?  
 5 A. I don't know that.  
 6 Q. You don't know that. Okay. You're not an analytical  
 7 chemist, are you?  
 8 A. No.  
 9 Q. And you know that analytical chemists have tools  
 10 available to them to analyze chemically what's in that mesh,  
 11 don't you?  
 12 A. That's what analytical chemists do.  
 13 Q. But you've not done that in your work in this case as any  
 14 analytical chemistry to determine what is chemically present  
 15 in the mesh. True?  
 16 A. This is not completely true. I did my histological  
 17 analysis using my histological tools to analyze what is  
 18 chemical composition.  
 19 Q. All right. So, to the extent that you used the dyes as  
 20 you talked about on your direct examination, that's chemistry  
 21 as far as you're concerned?  
 22 A. Yes.  
 23 Q. All right.  
 24 A. Dye is a chemical.  
 25 Q. Is that the extent of the chemistry that you did?

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1 documented, and sent it to Steelgate. They didn't perform  
 2 analysis.  
 3 Q. Thank you. Now, when the surgeon removed the mesh in  
 4 July, 2012, it was placed in formalin; correct?  
 5 A. That's correct.  
 6 Q. And when the surgeon removed the mesh during this  
 7 procedure, he used heat to remove the mesh?  
 8 A. By the examining of the specimen, it was not enough  
 9 cautery artifact there. If it was used, it was used really  
 10 gently because the beauty of the microscopy is I can see the  
 11 changes which can be caused by heat or by fixation. So, for  
 12 that specific specimen I did not see extensive cautery  
 13 artifact.  
 14 Q. Did you see any evidence of heat?  
 15 A. Not to a degree which would prevent me from analysis.  
 16 Q. Okay. Now, after the removal of this mesh explant,  
 17 you've already testified it was -- you had seven pieces and  
 18 you showed the jury a picture of that. Correct?  
 19 A. This is not correct. I had four pieces.  
 20 Q. I'm sorry. But you know that there were seven pieces  
 21 from the explant?  
 22 A. It's not on the boards.  
 23 Q. Oh, I'm sorry. No wonder I can't find it.  
 24 A. Are you looking for this photograph?  
 25 Q. Thank you. Have you -- you know there were seven pieces

Page 676

1 A. Both polarizing light and dyes. These are histological  
 2 tools.  
 3 Q. Okay. You received the four samples that you just showed  
 4 the jury. You talked about on direct examination this  
 5 formalin solution. Correct?  
 6 A. That's correct.  
 7 Q. And the tissue samples before they were placed in  
 8 formalin were covered in tissue; correct? The mesh had tissue  
 9 on it.  
 10 A. Well, the pieces came as mesh with tissue together.  
 11 Q. Right. And do you understand that that's the explant as  
 12 removed from Ms. Bellew?  
 13 A. Yes.  
 14 Q. And that's mesh with tissue on it; correct?  
 15 A. That's correct.  
 16 Q. And then it was placed in the formalin; correct?  
 17 A. That's correct.  
 18 Q. And you understand that formalin and tissue cross-links;  
 19 correct?  
 20 A. Repeat, please.  
 21 Q. You understand that formalin solution cross-links with  
 22 proteins that are in the tissue; correct?  
 23 A. That's correct. That's how it preserves tissue.  
 24 Q. Can you tell the jury the chemical reaction that occurs  
 25 when formalin cross-links with the tissues?

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1 A. Specific details?

2 Q. Yes.

3 A. I don't know specific details. It cross-links, binds

4 proteins together so they cannot be degraded by bacteria.

5 Q. And the formalin fixation is important because it

6 preserves the tissue on the mesh so it won't decay; correct?

7 A. That's correct.

8 Q. And the preservation of the tissue allows the pathologist

9 to study the tissue sample for potential disease; correct?

10 A. That's correct.

11 Q. And the formalin fixation hardens the tissue so it can be

12 sliced into the slides that you've analyzed here today;

13 correct?

14 A. No, this is not correct. Hardening or stiffening of the

15 tissues does occur, but it's not done for that purpose. The

16 purpose of formalin is to preserve tissue. It stiffens to a

17 degree.

18 Q. You agree that the formalin and protein cross-linking

19 stiffens the tissue, don't you?

20 A. That's correct.

21 Q. Now, you made no effort to clean the tissue or the

22 formalin from the mesh before you conducted -- you prepared

23 your slides in this case; correct?

24 A. I didn't understand the question. Did I remove formalin?

25 Q. Did you make any effort to clean the mesh before you did

Page 679

1 A. That's correct.

2 Q. And part of that process is to treat this mesh sample

3 with alcohol?

4 A. That's correct.

5 Q. And the alcohol that you use to treat this sample

6 sometimes causes the tissue to shrink?

7 A. To a degree.

8 Q. And you also treat this mesh sample with a material known

9 as xylene?

10 A. That's correct.

11 Q. And xylene is a solvent; correct?

12 A. Yes.

13 Q. And you know that xylene is a solvent to polypropylene?

14 A. I don't know about that.

15 Q. Okay. You've never analyzed the extent to which

16 polypropylene -- excuse me -- that xylene can act as a solvent

17 on polypropylene; correct?

18 A. I did.

19 Q. You, you --

20 A. I did place new mesh in xylene. It's been sitting for

21 eight months. The mesh didn't change.

22 Q. Have you analyzed that mesh chemically?

23 A. No, not chemically.

24 Q. I want to talk to you for a minute about -- I'll go back

25 to 1910-G. Do you remember talking to the jury about 1910-G?

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1 your slide preparation process? You didn't do that, did you?

2 A. What do you mean "clean"?

3 Q. Did you try to remove any material -- any formalin

4 material from the mesh before you did your slide preparation?

5 A. Formalin is being washed out. The processing works as --

6 the formalin is a water soluble substance. It needs to be

7 washed out of the tissue completely by alcohol. And then when

8 the tissue is completely dehydrated, then it can be processed

9 for dissection. So, formalin is removed. Tissue is not

10 removed. The formalin is removed.

11 Q. It's your testimony that the formalin is removed during

12 the sample preparation process?

13 A. Formalin solution, yes. The cross-linking molecules stay

14 there, but the formalin solution is being removed during

15 preparation.

16 Q. Okay. When you say the cross-linking stays there, the

17 cross-linking is the binding between the formalin and the

18 tissue; correct?

19 A. That's correct.

20 Q. And that remains?

21 A. That remains.

22 Q. Now, let's talk a little bit about the sample preparation

23 process. During this sample preparation process when you send

24 the mesh off to the histology department, that's something the

25 technologists, technicians did. You didn't do. Correct?

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1 A. Yes, I do.

2 Q. And this is the image that you described of a

3 polypropylene fiber; correct?

4 A. That's correct.

5 Q. And just to orient the jury a little bit, you talked

6 about this degradation bark?

7 A. That's correct.

8 Q. And that's about five microns thick; correct?

9 A. That's correct.

10 Q. And five microns -- how, how thick is a human hair?

11 About 70 microns?

12 A. That's correct. However, we cannot --

13 Q. Excuse me. I get to ask the questions right now.

14 MR. THOMAS: I'm sorry, Your Honor. Can I move to --

15 THE COURT: Yes. It's sustained.

16 MR. THOMAS: Thank you.

17 BY MR. THOMAS:

18 Q. And, so, this bark that's depicted here is about

19 five microns which is about 1/14th the size of a human

20 hair; correct?

21 A. Yes, but it's pipe-like.

22 Q. Now, Doctor, this is magnified, I think you told the

23 jury, a thousand times?

24 A. About a thousand times.

25 Q. All right. And this non-degraded core is what you have

Page 681

1 described as the polypropylene fiber; correct?

2 A. The non-degraded part of polypropylene fiber.

3 Q. All right. Now, we just talked a minute ago about the

4 sample preparation process, and when you use alcohol in the

5 sample preparation process that the tissue sometimes retracts

6 or shrinks.

7 A. That's correct.

8 Q. Now, this white area around the bark on Exhibit G is wax,

9 isn't it?

10 A. In that specific image it's clear space.

11 Q. Clear space?

12 A. What is being washed off.

13 Q. Okay. So, it's, it's -- meaning that during the sample

14 preparation, the tissue got pulled away from what you've

15 described as the bark.

16 A. That's correct.

17 Q. And what causes that to pull away like that? Tell the

18 jury.

19 A. Shrinking of the tissue because during formalin fixation

20 and processing, tissue shrinks slightly. And that's the

21 degree it shrinks.

22 Q. So, all of this area which is in white is open space?

23 A. Yes, that's correct.

24 Q. Now, you understand that the polypropylene fiber is a

25 circle, don't you?

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1 A. Not a circle. It's a solid rod.

2 Q. As you look at this, quote, non-degraded core, as you've

3 labeled it in 1910-G, this should be a circle, shouldn't it?

4 A. This is close to a circle.

5 Q. I'm sorry?

6 A. This is close to a circle. It's a bit oval, but it's

7 close.

8 Q. But it's not a circle, is it?

9 A. It's not a perfect circle. It's close to circle.

10 Q. Now, when we, when we make these slices, or when you make

11 these slices, you use a knife?

12 A. Yeah, a microtome.

13 Q. A microtome?

14 A. That's correct.

15 Q. And you cut these slices that are five microns thick;

16 correct.

17 A. About three to five microns, that's correct.

18 Q. That's thinner than a piece of paper, isn't it?

19 A. Yes.

20 Q. And once you make those slices, you put them in water and

21 then they're transferred onto a slide and adhered to the slide

22 with a material known as Permunt; correct?

23 A. Permunt is poured over to hold the crevices. Yes,

24 that's the process.

25 Q. And Permunt has toluene in it; correct?

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1 A. That's correct.

2 Q. And toluene is -- does not behave well with

3 polypropylene. Do you know that?

4 A. I don't know. As I said, I put one mesh in xylene and it

5 stays intact for several months.

6 Q. But you've not analyzed that chemically, have you?

7 A. No, I didn't.

8 Q. So, we have a white area around the polypropylene, that,

9 that open space; correct?

10 A. That's correct.

11 Q. And we have an oval polypropylene fiber that should be

12 round; correct?

13 A. Well, it's -- on this image it's more close to oval.

14 There are multiple -- I can show you that there are perfect

15 round sections.

16 Q. Okay. And the reason for that is because it may have

17 been cut at an angle; correct?

18 A. With a slight angle. If you can imagine if it's a rod,

19 if you take a tree trunk and angle it slightly, then it

20 becomes oval. To get it real oval you have to tilt it all the

21 way almost parallel to the section. So, in this specific

22 image, the filament was slightly tilted.

23 Q. Okay. So, is it fair for the jury to understand that

24 this slice, 1910-G, is cut at something of an angle as opposed

25 to straight across?

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1 A. At a small angle.

2 Q. And that explains the fact that this non-degraded core

3 appears as an oblong as opposed to a circle?

4 A. That's correct.

5 Q. All right. Now, you agree that non-degraded

6 polypropylene does not stain; correct?

7 A. That's correct.

8 Q. And tell the jury why it doesn't stain.

9 A. Because the structure of polypropylene is solid, so it

10 doesn't have cavities to trap dyes. It's like aluminum. You

11 cannot stain aluminum. To stain aluminum, we need to oxidize

12 it, to build this porous layer of oxidation. And then it can

13 trap dyes, and then we can analyze aluminum parts, all those

14 shiny aluminum parts. It's the same process. It's a layer of

15 porous material on a solid surface.

16 Q. Now, Doctor, isn't it true that typically an H&E stain,

17 hematoxylin and eosin stain leaves their colors by a chemical

18 reaction?

19 A. Not exactly chemical reaction. Most of the dyes -- there

20 are different types of dyes. Most of the dyes are trapped.

21 So, it's not fully chemical reaction when molecules form new

22 molecules. It's more of a trapping or binding of the dye

23 molecules inside the material.

24 Q. Let me ask you this. Do you agree with this statement:

25 That staining is not simply coloring the sections

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1 randomly, but depends on using differences in the chemistry of  
2 the tissues to show the various components and different  
3 colors. This is most commonly done by using dyes that can  
4 bind the tissues in a selective way.

5 Do you agree with that?

6 A. Not entirely. Some stains are not specific. They stain  
7 everything. As I said, everything porous will trap those  
8 dyes. And some stains are designed specifically for specific  
9 components. So, you cannot assume that all stains work the  
10 same way. They're different.

11 Q. Let me ask you if you agree with this statement:

12 The binding of dyes to tissues is no different to any  
13 other chemical bound, bonding, so the mechanisms rely on the  
14 same binding forces that occur in all other organic compounds.  
15 The dyes must form some form of bond or link to the tissue or  
16 they will simply rinse out of the tissue when the section is  
17 washed in another reagent.

18 Do you agree with that?

19 A. That was a long sentence. I can say that there is some  
20 process of binding of the dye to the tissue either by chemical  
21 or trapping mechanically. But there is a binding of the dye  
22 in the tissue or any other material.

23 Q. Well, the H&E stain can be broken down into hematoxylin  
24 and eosin; correct?

25 A. That's correct.

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1 hematoxylin stain is applied, you rinse it with water to rinse  
2 out any stain that's just on the sample so that you leave the  
3 hematoxylin that is bound with the negatively charged tissue  
4 materials.

5 A. To a degree. It's not completely clear. It's still  
6 purple if you don't do eosin.

7 COURT REPORTER: Excuse me?

8 THE WITNESS: If you don't -- it's not -- it doesn't  
9 wash away completely. There is still purple staining if you  
10 do not stain it with eosin. The red color just overwhelms  
11 purple on the top of it.

12 Q. And the same thing is true with eosin. Eosin stains  
13 pink; correct?

14 A. That's correct.

15 Q. And eosin is negatively charged and binds with positively  
16 charged materials in the body; correct?

17 A. As far as I remember, that's the mechanism.

18 Q. Do you know the mechanism?

19 A. I don't remember exactly what happens with eosin, but I  
20 think you're right.

21 Q. Okay. Thank you. And do you know what charge  
22 polypropylene has?

23 A. No.

24 Q. Polypropylene has no charge, does it?

25 A. I don't know.

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1 Q. And hematoxylin stains blue?

2 A. Yes.

3 Q. And hematoxylin is also a positively charged ion, isn't  
4 it?

5 A. That's another way of binding with positive or negative  
6 charge.

7 Q. And the hematoxylin, a positive ion, binds with  
8 negatively charged substances in the body; correct?

9 A. Yes. However, --

10 Q. Excuse me. And they stain those blue; correct?

11 A. You have a different shade.

12 Q. Is your answer "yes" or "no"? "Can you answer "yes" or  
13 "no"?"

14 A. I cannot answer "yes" or "no" because it's not black and  
15 white. When the hematoxylin is applied to the tissue, it  
16 stains all structures. Then you have to differentiate. You  
17 have to wash it out. And then there is a second chemical.  
18 Then there is water applied.

19 So, it becomes bluer and is being washed from the  
20 structures which trap the dye non-specifically. So, only  
21 those dyed molecules which are still holding by electrical  
22 charge are holding. But those molecules which are just  
23 trapped in the pores are being washed away. This is a process  
24 of differentiation during staining.

25 Q. And that's exactly my point, Doctor, is that after the

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1 Q. And that's why none of these stains bind to  
2 polypropylene; correct?

3 A. To non-degradable polypropylene.

4 Q. You agree with me the fact that polypropylene has no  
5 charge is the reason why neither hematoxylin or eosin bind to  
6 polypropylene; correct?

7 A. I don't know.

8 Q. You don't know. You never studied that issue?

9 A. I see that it doesn't stain when it's not degraded. When  
10 it's degraded, it stains.

11 Q. Okay. Now, you have offered the opinion that this is,  
12 this degraded, what you call bark is oxidized polypropylene;  
13 correct?

14 A. Degraded polypropylene.

15 Q. I think you called it oxidized polypropylene.

16 A. Oxidized polypropylene.

17 Q. And can you tell the jury the chemical structure of  
18 oxidized polypropylene?

19 A. No, I cannot.

20 Q. All right. Do you know the positive or negative  
21 components of oxidized polypropylene?

22 A. No.

23 Q. Do you know whether there are any materials in oxidized  
24 polypropylene for either eosin or hematoxylin to bind?

25 A. Can you repeat the question?

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- 1 Q. Sure. Are there any chemical components in oxidized  
2 polypropylene that would allow either hematoxylin or eosin to  
3 bind?  
4 A. It doesn't bind to chemical components. It's being  
5 trapped in the pores and crevices.  
6 Q. It's fair to say, isn't it, Doctor, that you're not an  
7 expert in the direct oxidation of polypropylene?  
8 A. That's correct.  
9 Q. And your opinion is that oxidized polypropylene, this  
10 bark, has cracks or crevices in it that retain the stain?  
11 A. That's my opinion.  
12 Q. And, so, in order for that to retain the stain, that  
13 means that this material is going to have to hold the stain  
14 even during the washing process during the sample preparation  
15 process we talked about; correct?  
16 A. That's correct, as long as washing doesn't wash it  
17 completely because if you extend washing to a degree when it  
18 starts washing, the staining fades.  
19 Q. Now, again, you've used a light microscope here that  
20 magnifies up to about a thousand times?  
21 A. That's correct.  
22 Q. And it's your belief that this oxidized polypropylene has  
23 cracks in it on the order of ten nanometers?  
24 A. So, I measured them --  
25 Q. Excuse me. Did you measure Ms. Bellew's mesh?

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- 1 A. No.  
2 Q. You did not?  
3 A. Well, if you ask me about cracks, I can tell you what's my  
4 opinion about cracks.  
5 Q. It's about ten nanometers, isn't it?  
6 A. It depends on the crack.  
7 Q. Okay.  
8 A. Some of them larger, some of them smaller.  
9 Q. But you've not, you've not measured any cracks in the  
10 bark for Mrs. Bellew, have you?  
11 A. No. I have no purpose for that.  
12 Q. Now, one micron is about the limit of what you can see by  
13 light microscopy, isn't it?  
14 A. Or half micron depending how good the lenses are.  
15 Q. And it's fair to say that your light microscope is not  
16 able to detect any cracks in the degraded polypropylene that  
17 would hold this stain; correct?  
18 A. Those -- the very small pores and crevices which hold?  
19 Q. Yes.  
20 A. That's correct. I cannot see that. They are too small.  
21 Q. So, this is something that you have just concluded based  
22 upon what you believe must be happening in Ms. Bellew's mesh  
23 that these cracks or crevices retain this dye that show up on  
24 this slide. Correct?  
25 A. This is not just conclusion based on this specimen. This

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- 1 is based on my knowledge, training, and experience and  
2 examination of this specimen and many others.  
3 Q. Now, Doctor, just so the jury understands, it's your  
4 opinion that this polypropylene, Prolene polypropylene -- by  
5 the way, you know that Prolene polypropylene has special  
6 additives added to it?  
7 A. Yes. The polypropylene has antioxidants to prevent  
8 degradation. It slows it down but it doesn't stop it.  
9 Q. And that's what makes Prolene different from other  
10 polypropylene. You know that, don't you?  
11 A. You mean other mesh devices?  
12 Q. Other, other polypropylene used in mesh. You know that's  
13 what makes it different, don't you?  
14 A. I do not know the exact difference. I'm not a material  
15 scientist.  
16 Q. And you know the material that makes up polypropylene,  
17 Prolene polypropylene is made here in West Virginia, don't  
18 you?  
19 A. I don't know.  
20 Q. Okay. Now, you could have taken a piece of polypropylene  
21 and intentionally oxidized it and then washed it with stains  
22 to see if there were, in fact, cracks or crevices that held  
23 these dyes, couldn't you?  
24 A. Yes, I could.  
25 Q. But you didn't do that, did you?

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- 1 A. It's a work in progress. I put --  
2 Q. But you haven't done that for this case?  
3 A. It's not finished. For this case, no.  
4 Q. Okay. Thank you. And if you had a piece of oxidized  
5 polypropylene that you stained and it held dyes, that would  
6 support your opinion, wouldn't it?  
7 A. That's correct.  
8 Q. And you talked before about this formalin control that  
9 you did. And, that is, you took a piece of pristine mesh and  
10 you put it in formalin so that you could make sure that this  
11 sample preparation process didn't damage the polypropylene as  
12 it went through the sample preparation process. Correct?  
13 A. Formalin fixation and sample preparation process.  
14 Q. Okay. When you did -- and that's called a controlled  
15 experiment?  
16 A. That's correct.  
17 Q. And that's so you can control for anything that might go  
18 wrong. In the sample preparation process, you want to make  
19 sure that doesn't confound what you find in your opinions.  
20 Correct?  
21 A. That's correct.  
22 Q. And when you did your formalin controlled experiment, you  
23 did not include tissue in that formalin controlled experiment,  
24 did you?  
25 A. That's correct. That was the whole purpose.



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1 Q. And you didn't include any human serum in that formalin  
2 controlled experiment; correct?  
3 A. That's correct. That's the whole purpose, just formalin.  
4 Q. And the, the -- you were unable to tell the impact of the  
5 cross-linking of formalin and protein on your control in your  
6 sample preparation process; correct?  
7 A. That's correct. I wanted to avoid all tissue -- all  
8 foreign tissue.  
9 Q. Now, Doctor, you testified that the Prolift mesh for  
10 Ms. Bellew had folds in it; correct?  
11 A. Yes.  
12 Q. And you don't know whether those folds formed before or  
13 after the operation, do you?  
14 A. Which operation?  
15 Q. The implant operation.  
16 A. Some of them were formed during surgery and some of them,  
17 smaller wrinkles, during scar contracture.  
18 Q. Doctor, do you remember when you gave a deposition in  
19 this case in August, 2014?  
20 A. Yes.  
21 Q. And on Page 155 do you remember being asked the  
22 question -- can I have that please -- 155, lines 5 through 11.  
23 You were asked the question:  
24 "Are you saying that the surgeon put it in and put  
25 folds in there at the time it was planted?"

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1 "I don't know how, when they formed, intraoperative,  
2 post-operative."  
3 Did I read that correctly?  
4 A. That's correct.  
5 Q. And you agree that Mrs. Bellew did not have a mesh  
6 erosion. You agree with that, don't you?  
7 A. I can only state what I saw in the specimen.  
8 Q. Again, let's turn to your deposition again on Page 166,  
9 166, lines 3 through 5.  
10 "Question: Well, Mrs. Bellew didn't have an erosion."  
11 "Answer: No."  
12 Did you give that answer at the time of your  
13 deposition?  
14 A. Yes. I didn't see it on the specimen.  
15 Q. And you testified a lot on direct examination about  
16 nerves that you saw on the slides?  
17 A. That's correct.  
18 Q. And you agree that seeing the nerves in these slides does  
19 not tell you that any of the pain mechanisms did, in fact,  
20 occur in Mrs. Bellew. You agree with that, don't you?  
21 A. No, I don't agree.  
22 Q. It's true that the feeling of pain is a subjective  
23 complaint of a patient. Do you agree with that?  
24 A. That's correct.  
25 Q. And in order to find pain, the patient has to tell you

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1 there is pain; is that correct?  
2 A. That's correct.  
3 Q. Let me direct your attention to Page 172 of your  
4 deposition, lines 6 through 13.  
5 "Question: But seeing a nerve doesn't tell you that  
6 any one of those mechanisms actually did, in fact, occur."  
7 Your answer: "Feeling of pain is a subjective  
8 sensation of a patient. So, to say there was a pain, it would  
9 have to be a patient who tells you that there is a pain.  
10 Seeing a nerve in the section, I can only assess a risk of it  
11 or possibility."  
12 Did I read that correctly?  
13 A. That's correct.  
14 MR. ANDERSON: Excuse me, Your Honor. I would ask  
15 that he read the entire answer by the witness from the  
16 deposition. He stopped it off at the middle of his answer.  
17 THE COURT: It may be done.  
18 BY MR. THOMAS:  
19 Q. "For example, on this specific picture, the degree  
20 of deformation of these nerves at Page 100 of your  
21 report would have a very high probability to be painful.  
22 Is it your opinion that those nerves on Page 100 of the  
23 report are actually causing her to sense pain?"  
24 "My opinion is that these deformation of these nerves  
25 carries high degree of probability to cause pain."

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1 "But you can't say when those nerves were formed. You  
2 can't say whether those nerves were pre-existing in that  
3 manner."  
4 Answer: "No."  
5 Is that enough?  
6 MR. ANDERSON: Yeah.  
7 THE WITNESS: That's correct.  
8 BY MR. THOMAS:  
9 Q. Now, we decided you're not an analytical chemist.  
10 You've not consulted with an analytical chemist in this  
11 case; correct?  
12 A. That's correct.  
13 Q. And there are also scientists who look at the material  
14 properties of, of implants; correct? Material scientists?  
15 A. Yes, there are material scientists.  
16 Q. And, and you're not a material scientist?  
17 A. No, I'm not.  
18 Q. And you've not consulted with a material scientist in  
19 your work in this case; correct?  
20 A. That's correct.  
21 Q. Now, you used a light microscope that magnifies up to a  
22 thousand times?  
23 A. That's correct.  
24 Q. And you're aware of a technology known as Scanning  
25 Electron Microscopy, aren't you?

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1 A. That's correct. I use Transmission Electron Microscopy.  
 2 Q. Okay. But you didn't use Transmission Electron  
 3 Microscopy in this case; correct?  
 4 A. No. It's very expensive and time consuming.  
 5 Q. Okay. And you didn't use Scanning Electron Microscopy in  
 6 this case; correct?  
 7 A. No. It's not the standard of care.  
 8 Q. And you don't think the Scanning Electron Microscopy  
 9 answers any questions for degradation analysis; is that  
 10 correct?  
 11 A. If it's used in the right hands, it can answer some  
 12 questions.  
 13 MR. THOMAS: I'm sorry, Your Honor.  
 14 BY MR. THOMAS:  
 15 Q. Now, let's talk a little bit about how these  
 16 stains -- how these slides are prepared. Again, this is  
 17 something that you asked somebody to do for you?  
 18 A. Our histotechnologists.  
 19 Q. And it's routine for you to refer pathology specimens to  
 20 your histotechnologists to prepare these slides for you to  
 21 analyze?  
 22 A. This is a routine procedure. All specimens go through  
 23 the same routine.  
 24 Q. And have you studied the procedure that the  
 25 histotechnologist goes through in order to put this material

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1 (DEFENDANT'S EXHIBIT 10493 RECEIVED IN EVIDENCE.)  
 2 BY MR. THOMAS:  
 3 Q. If we look at Paragraph 3. And this is the process  
 4 that these mesh explants went through as they were first  
 5 placed in paraffin before they were cut into slides;  
 6 correct?  
 7 A. That's correct.  
 8 Q. And you see that for 16 hours they were exposed to  
 9 different levels of ethanol and xylene; correct?  
 10 A. Correct.  
 11 Q. Am I right that the slides that you used and you talked  
 12 about today went through the sample preparation process? Am I  
 13 correct?  
 14 A. You are correct.  
 15 Q. Thank you. And the ethanol baths that we've talked about  
 16 are what caused the tissues to retract?  
 17 A. Not just ethanol, but --  
 18 Q. I'm sorry?  
 19 A. Not just ethanol, but dehydration through ethanol gives a  
 20 degree of shrinking, and also formalin.  
 21 Q. And the point of the ethanol is to remove the water;  
 22 correct?  
 23 A. That's correct.  
 24 Q. And then the xylene is designed to remove the ethanol?  
 25 A. That's correct.

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1 first in paraffin?  
 2 A. I don't understand.  
 3 Q. Let me, let me help you a minute. Let's bring up  
 4 Defendant's Exhibit 10493.  
 5 Let me show you what's been marked as Defendant's  
 6 Exhibit --  
 7 MR. THOMAS: I'm sorry. I gave you the wrong one,  
 8 Ben.  
 9 Excuse me, Your Honor.  
 10 BY MR. THOMAS:  
 11 Q. Doctor, I've handed you what's been marked as  
 12 Defendant's Exhibit 10493 and ask you if you recognize  
 13 that as the standard protocol for formalin fixed  
 14 paraffin embedded tissue at your hospital?  
 15 A. That's correct. I provided them to you.  
 16 Q. And this describes the process that your  
 17 histotechnologists use to put the blue samples into paraffin;  
 18 correct?  
 19 A. It's a standard procedure. It's used all over North  
 20 America.  
 21 Q. Okay. And if you look --  
 22 MR. THOMAS: Your Honor, I offer Defendant's Exhibit  
 23 10493.  
 24 THE COURT: Without objection.  
 25 MR. ANDERSON: No objection, Your Honor.

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1 Q. And the xylene is the solvent?  
 2 A. That's correct.  
 3 Q. You know it's inappropriate to put xylene in a  
 4 polypropylene container? Do you know that?  
 5 A. I don't know that.  
 6 Q. Let's go to Paragraph 4, please. "Trim paraffin blocks  
 7 as necessary and cut at three to ten microns (five microns is  
 8 commonly used.)"  
 9 And these are the slides that we talked about; correct?  
 10 A. Yeah. Those were cut at three microns.  
 11 Q. Three microns. The slides that you have here?  
 12 A. Yes, that's correct.  
 13 Q. Okay. So -- and just so the jury understands, you've  
 14 testified that this bark is about five microns?  
 15 A. Yes.  
 16 Q. So, the, the thickness of this slide magnified a thousand  
 17 times would be something less than the side of the bark?  
 18 A. That's correct.  
 19 Q. Okay. And then you cook the slides in an oven overnight?  
 20 A. Most of them get dried in 60 degrees.  
 21 Q. Okay. Centigrade?  
 22 A. Centigrade, yes.  
 23 Q. And that's after you apply toluene to it?  
 24 A. Yes.  
 25 Q. Do you know the impact of heat, xylene, and toluene on

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1 polypropylene?  
 2 A. Yes, I do.  
 3 Q. Have you studied it chemically?  
 4 A. As I said, I put pristine mesh and subjected it to the  
 5 same procedures and it didn't degrade.  
 6 Q. Have you studied it chemically?  
 7 A. Chemically you mean like a chemical scientist?  
 8 Q. Analytical chemist.  
 9 A. I'm not analytical chemist.  
 10 Q. And you've not asked any analytical chemist to look at  
 11 that, have you?  
 12 A. No.  
 13 Q. Then after the slides are prepared, that's when you stain  
 14 it; correct?  
 15 A. That's correct.  
 16 Q. Doctor, I've handed you a copy of what's been marked as  
 17 Defendant's Exhibit 10495. Do you recognize that as the  
 18 protocol sheet for the staining of slides at St. Michael's?  
 19 A. Yeah. I provided those to you.  
 20 MR. THOMAS: All right. Your Honor, I move admission  
 21 of Defendant's Exhibit 10495.  
 22 MR. ANDERSON: No objection.  
 23 THE COURT: May be admitted.  
 24 (DEFENDANT'S EXHIBIT 10495 RECEIVED IN EVIDENCE.)  
 25 BY MR. THOMAS:

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1 Q. And you note, Doctor, that the first step of this  
 2 is to put the slide in an oven at 65 degrees Centigrade?  
 3 A. That's correct.  
 4 Q. Do you know what temperature that is Fahrenheit?  
 5 A. That's a difficult question.  
 6 Q. That's okay.  
 7 A. Over 100 degrees.  
 8 Q. Okay. And then it's exposed to three separate baths of  
 9 xylene?  
 10 A. That's correct.  
 11 Q. And then three separate baths of alcohol?  
 12 A. That's correct.  
 13 Q. And then you wash it with water?  
 14 A. Yes. It's being saturated with water. It's the process  
 15 of re-saturation.  
 16 Q. Okay. And then you add your dye; correct? The  
 17 hematoxylin?  
 18 A. Then it goes to dye, either hematoxylin or anything else.  
 19 It depends on what staining that I want.  
 20 Q. Well, this one specifically is for hematoxylin and eosin;  
 21 correct?  
 22 A. That's correct.  
 23 Q. And step nine on this protocol is for hematoxylin;  
 24 correct?  
 25 A. Yes. But all steps from one to eight will be the same

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1 for any other stain.  
 2 Q. And then after the hematoxylin is applied, then you go  
 3 through a series of definition, water, blue buffer, water, and  
 4 alcohol; correct?  
 5 A. That's correct.  
 6 Q. And that's to wash off any dye that doesn't chemically  
 7 bind; correct?  
 8 A. Excessive dye, that's correct.  
 9 Q. Okay.  
 10 A. It's not a perfect washing off. There's still some  
 11 remaining.  
 12 Q. And the same is true for the next step where you -- in  
 13 step number 12 -- 16, I'm sorry, where you add the eosin dye;  
 14 correct?  
 15 A. That's correct.  
 16 Q. And then you go through three baths of alcohol and two  
 17 baths of xylene and then you're done?  
 18 A. Not yet.  
 19 Q. Well, in terms of the staining process.  
 20 A. Xylene is not staining anymore. Xylene is preparation  
 21 for mounting.  
 22 Q. Right. But in terms -- then you go to the Permount where  
 23 you put on the cover slip and you put the Permount in order to  
 24 seal the tissue into place so you can look at it?  
 25 A. Yes. With the formalin you can put water in it and

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1 you'll get the same appearance.  
 2 Q. Okay. But my point is after you apply the eosin, you  
 3 rinse with alcohol and rinse with xylene; correct?  
 4 A. That's correct.  
 5 Q. And the goal there again is to remove any eosin that's  
 6 not bound to tissue?  
 7 A. Alcohol, yes; xylene, no.  
 8 Q. Okay.  
 9 MR. THOMAS: Your Honor, may I have a minute, please?  
 10 THE COURT: Yes.  
 11 (Pause)  
 12 BY MR. THOMAS:  
 13 Q. Doctor, do you see live patients in your practice?  
 14 A. Yes, I do.  
 15 Q. Okay. Do you counsel or treat patients for dyspareunia?  
 16 A. No.  
 17 Q. Do you know that there are differences among people,  
 18 among people that have dyspareunia?  
 19 A. What do you mean? What differences?  
 20 Q. Do you know that there are any differences? Do you think  
 21 dyspareunia is the same in all people?  
 22 A. No, I don't believe that.  
 23 Q. Okay. And do you prescribe any kind of medication for  
 24 pain?  
 25 A. No, not anymore.

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1 Q. Did you analyze any other tissue removed from Ms. Bellew  
2 in this case other than the ones you described, the four?

3 A. No.

4 Q. You didn't examine any of the tissue for the adhesions or  
5 the scars, scarring that may have been removed from  
6 Ms. Bellew, did you?

7 A. What do you mean? The whole piece was just scar.

8 Q. That's all you -- to the extent that she had other tissue  
9 removed at other times for scarring or adhesions, you didn't  
10 analyze that tissue, did you?

11 A. No, I didn't analyze anymore tissue. I analyzed this  
12 specimen.

13 Q. Did you know that adhesions and scarring can cause pain?

14 A. Yes, it can.

15 MR. THOMAS: That's all I have. Thank you, Doctor.

16 THE COURT: All right. Next witness, please. I'm

17 sorry, redirect. I apologize.

18 (REDIRECT EXAMINATION OF VLADIMIR IAKOVLEV BY MR. ANDERSON:)

19 Q. Let's pick up with that last question. You said that you  
20 reviewed the medical records of Ms. Bellew?

21 A. Yes.

22 Q. What happened every time, from the medical records, that  
23 Dr. DeHase removed a chunk of mesh from Ms. Bellew with  
24 regard to her pain?

25 A. There was improvement and change in symptoms of pelvic

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1 Microscopy or this SEM that he talked about or TEM, this  
2 Transmission Electron Microscopy, to be able to come in and  
3 tell the jury that that's cracked polypropylene?

4 A. No.

5 Q. Did you need any of that?

6 A. I mean, you can see it clearly.

7 Q. Counsel talked to you a little bit about whether or not  
8 you knew that this cracked bark was polypropylene. Do you  
9 recall that part of your testimony? Do you recall that part  
10 of your testimony?

11 A. Yes.

12 Q. If this was protein, would it polarize light?

13 A. Not to that degree. The strongest protein if it's  
14 cross-linked with formalin, in this image you see the darkness  
15 of it.

16 Q. So, if this was protein, would it glow bright purple like  
17 that?

18 A. I have not seen anything in the human body that rises to  
19 that degree. The only object naturally occurring to the body  
20 to this degree is crystals. That's uric acid crystals or  
21 pyrophosphate crystals. That's how we diagnose.

22 Some cell samples also polarize like this. I performed  
23 calcium stain. I checked for it because calcium will be  
24 brittle and won't polarize. In this calcium stain it was  
25 negative. This material doesn't contain any calcium.

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1 pain located in the area.

2 Q. And did you review the medical records about this  
3 granulation tissue that counsel just mentioned?

4 A. Yes.

5 Q. Did that granulation tissue have any hardened, sclerosed,  
6 polypropylene mesh in it?

7 A. No.

8 Q. When they removed that, was there any pain noted in the  
9 record related to the granulation tissue?

10 A. There was some discomfort as I understand, but it was  
11 transient. It was removed and it cured.

12 Q. Counsel talked a lot about degradation. Even forgetting  
13 about degradation, was that the only cause of all the chronic  
14 inflammation that you talked about, the fibrotic bridging, the  
15 scar plates, the scar encapsulation, the contraction, and the  
16 pain in Ms. Bellew?

17 MR. THOMAS: Your Honor, that's beyond the scope.

18 THE COURT: Overruled.

19 BY MR. ANDERSON:

20 Q. Is this the only cause of all the inflammation that  
21 we saw in these other images?

22 A. No. This is more of an interesting finding. But the  
23 real finding, what I do as a pathologist is scarring,  
24 inflammation, nerves, traumatic neuroma.

25 Q. Did you continue to do expensive Scanning Electron

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1 Q. Another question for you, Doctor. You were asked a  
2 number of questions about these protocols about xylene,  
3 hexylene, benzene, a number of things off these documents by  
4 counsel. Do you remember being asked questions about that?

5 A. That's correct.

6 Q. Did you follow standard operating procedures used by  
7 pathologists all across North America when you prepared these?

8 A. Yes.

9 Q. Would any of these things that counsel listed off and put  
10 up there for the jury, xylene, alcohol, hematoxylin, blue  
11 buffer, 95 percent alcohol, does that have anything to do with  
12 the scarring that we see in Plaintiff's Exhibit 1910-DD?

13 A. No. You cannot make nerves grow into the mesh. You  
14 cannot make scar grow into the mesh. It only happens in the  
15 body. The only thing which can do it is human tissue, again  
16 growing the mesh, formed scars around it, formed inflammation  
17 around it, and deformed nerves.

18 Q. Do you need to be a material scientist to tell the jury  
19 that?

20 A. No, because this is my science. This is what I was  
21 trained to do.

22 MR. ANDERSON: No further questions.

23 THE COURT: All right. May the witness be excused?

24 MR. THOMAS: Yes, Your Honor.

25 THE COURT: All right.

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1 Thank you, Doctor.  
 2 Call your next witness.  
 3 MR. SLATER: Thank you, Your Honor.  
 4 Your Honor, we now call -- it's a brief video --  
 5 Dr. Vincent Lucente.  
 6 THE COURT: Ladies and gentlemen, we will have  
 7 testimony by videotape. Remember, this testimony was taken  
 8 under oath and is to be treated by you in the same way and  
 9 evaluated by you in the same way as testimony presented here  
 10 in open court.  
 11 (The videotaped direct testimony of Vincent Lucente  
 12 was played from 11:47 a.m. until 11:50 a.m.)  
 13 MR. SLATER: Our next witness, Your Honor, would take  
 14 about 20 minutes, so it's up to the Court. We tried to time  
 15 it. We were estimating. So, we could -- we're happy to play  
 16 it if you want to go over about eight or nine minutes past  
 17 12:00. Otherwise, it's up to the Court, Your Honor. That's  
 18 the one we have cued up and ready to go.  
 19 THE COURT: It's 11:50. We'll take lunch and come  
 20 back at 12:50. Don't discuss the case among yourselves or  
 21 permit anyone to discuss it with you or in your presence.  
 22 Don't use any digital device, read anything, listen to  
 23 anything, or watch anything about the case. Have a great  
 24 lunch.  
 25 Court's in recess until 12:50.

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1 (Luncheon recess taken at 11:50 a.m.)  
 2 (The Jury entered the courtroom at 12:54 p.m.)  
 3 THE OFFICER: All rise.  
 4 THE COURT: Good afternoon. Do you think we need to  
 5 put a regular chair back up there for the witness?  
 6 THE DEPUTY CLERK: Well, do you want the regular  
 7 chair back up there for the witness?  
 8 THE COURT: It's up to --  
 9 MR. ANDERSON: I'm happy to do it, Judge.  
 10 THE COURT: Well, it doesn't really matter to me. It  
 11 just seems like it's easier to sit in than the straight chair.  
 12 We can do it on the break.  
 13 MR. ANDERSON: Okay. Sorry.  
 14 THE COURT: All right. Call your next witness.  
 15 Yes, sir?  
 16 MR. THOMAS: Thank you, Your Honor. I neglected to  
 17 move into evidence defendants' Exhibit 10041 under  
 18 Dr. Iakovlev's testimony. I do that now.  
 19 THE COURT: I neglected to admit it. I'll remedy  
 20 that now.  
 21 MR. ANDERSON: No objection, Your Honor.  
 22 THE DEPUTY CLERK: Thank you.  
 23 MR. THOMAS: Thank you, Your Honor.  
 24 (DEFENDANTS' EXHIBIT D-10041 WAS RECEIVED IN EVIDENCE.)  
 25 THE COURT: Mr. Slater?

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1 MR. SLATER: Thank you very much, Your Honor. We now  
 2 call by video Scott Ciarrocca, project leader, the Prolift  
 3 project, Your Honor.  
 4 THE COURT: All right. Ladies and gentlemen, a  
 5 witness by video deposition. Treat the testimony and evaluate  
 6 it in the same way you would live testimony in court.  
 7 (The videotaped direct testimony of Scott Ciarrocca  
 8 was played from 12:56 p.m. to 1:19 p.m.)  
 9 MR. SLATER: Your Honor, that's all the testimony of  
 10 Scott Ciarrocca.  
 11 Plaintiffs will offer into evidence P-2137, P-0968,  
 12 P-0368, P-0975, and I think we are going to also be moving the  
 13 clip reports -- we are going to hold the clip reports. I  
 14 think they should be marked as an exhibit number, I think, so  
 15 I'm going to offer these documents and we will reconcile the  
 16 clip reports at a break.  
 17 THE COURT: Is there an objection?  
 18 MR. THOMAS: They just gave them to me, Your Honor.  
 19 I'm sorry. Let me look at them real quickly. 975, 2137, 968  
 20 and 368?  
 21 MR. SLATER: Yes.  
 22 MR. THOMAS: No objection, Your Honor.  
 23 THE COURT: Exhibits may be received in evidence.  
 24 MR. SLATER: Thank you, Your Honor.  
 25 (PLAINTIFF EXHIBITS P-2137, P-0968, P-0368, AND P-0975 WERE

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1 RECEIVED IN EVIDENCE.)  
 2 THE COURT: Is there cross-examination?  
 3 MR. THOMAS: We reserve cross-examination, Your  
 4 Honor.  
 5 THE COURT: Ladies and gentlemen, the defendants have  
 6 chosen to wait until their case to take testimony from this  
 7 witness, if they decide to.  
 8 Witness?  
 9 MR. SLATER: Yes, Your Honor. We now call Sean  
 10 O'Bryan who was the regulatory affairs project leader for the  
 11 Prolift project, Your Honor.  
 12 (The videotaped direct testimony of Sean O'Bryan was  
 13 played from 1:21 p.m. to 1:39 p.m.)  
 14 MR. SLATER: That's the direct testimony, Your Honor.  
 15 Plaintiffs will offer into evidence P-0980, P-1010,  
 16 P-2-112, and P-0678.  
 17 THE COURT: May be received.  
 18 (PLAINTIFF EXHIBITS P-0980, P-1010, P-2-112, and P-0678 WERE  
 19 RECEIVED IN EVIDENCE.)  
 20 THE COURT: Cross-examination?  
 21 MR. SLATER: I believe so, Your Honor.  
 22 MS. JONES: We do, Your Honor.  
 23 THE COURT: All right.  
 24 (The videotaped cross-examination testimony of Sean  
 25 O'Bryan was played from 1:39 p.m. to 1:47 p.m.)



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1 MS. JONES: That concludes the cross-examination.  
2 THE COURT: Is there redirect?  
3 MR. SLATER: There is a brief redirect, Your Honor.  
4 THE COURT: All right.  
5 (The videotaped redirect testimony of Sean O'Bryan  
6 was played from 1:47 p.m. to 1:48 p.m.)  
7 THE COURT: All right. Call your next witness.  
8 MR. SLATER: Your Honor, we call Charlotte Owens who  
9 was the worldwide medical director at the time of the launch  
10 of the Prolift.  
11 THE COURT: Is that by video?  
12 MR. SLATER: Yes, it is.  
13 THE COURT: Same instruction. Is that adequate?  
14 MR. SLATER: Everyone was invited; no one wanted to  
15 come.  
16 THE COURT: No, I want to make it clear that for  
17 reasons, some of which I explained to you, including the power  
18 of subpoena, these people are not here, but this testimony was  
19 taken under oath and you're to consider it the same as any  
20 other testimony. It's just a little harder to watch.  
21 MR. SLATER: Thank you, Your Honor.  
22 (The videotaped direct testimony of Charlotte Owens  
23 was played from 1:49 p.m. to 2:15 p.m.)  
24 MR. SLATER: Your Honor, that's the direct.  
25 Plaintiff offers Exhibit P-1545, P-2112, P-1010,

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1 P-0971, P-1507, as exhibits, and for learned treatises,  
2 P-2880.  
3 THE COURT: Is there objection?  
4 MR. THOMAS: No objection, Your Honor.  
5 THE COURT: May be received, exhibits as evidence and  
6 the learned treatise as a learned treatise.  
7 (PLAINTIFF'S EXHIBITS P-1545, P-2112, P-1010, P-0971, AND  
8 P-1507 WERE RECEIVED IN EVIDENCE, AND P-2880 AS LEARNED  
9 TREATISE.)  
10 THE COURT: Is there cross?  
11 MR. THOMAS: Yes, Your Honor, there is.  
12 (The videotaped cross-examination testimony of  
13 Charlotte Owens was played from 2:16 p.m. to 2:33 p.m.)  
14 MR. THOMAS: Your Honor, that concludes the  
15 examination of Ms. Owens, Dr. Owens.  
16 THE COURT: All right. Any exhibits?  
17 MR. THOMAS: Defendants offer defendants' Exhibit  
18 25867.  
19 THE COURT: Without objection?  
20 MR. SLATER: No objection.  
21 (DEFENDANTS' EXHIBIT D-25867 WAS RECEIVED IN EVIDENCE.)  
22 MR. SLATER: Your Honor, we have -- the next cut is  
23 five minutes of the next witness if you want to knock it off.  
24 THE COURT: Let's go ahead and do it, and then we  
25 will take our afternoon break.

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1 MR. SLATER: That would be great for us on  
2 scheduling.  
3 Our next witness is Kimberly Hunsicker from Ethicon  
4 Clinical Affairs. It's about five minutes.  
5 THE COURT: All right.  
6 (The videotaped direct testimony of Kimberly  
7 Hunsicker was played from 2:34 p.m. to 2:39 p.m.)  
8 MR. SLATER: That concludes the video.  
9 THE COURT: Is there cross?  
10 MS. JONES: No, Your Honor.  
11 THE COURT: All right, ladies and gentlemen, we'll  
12 take our afternoon break. During the break, don't discuss the  
13 case, don't communicate about it in any way. I'll call you  
14 back in 15 minutes.  
15 THE DEPUTY CLERK: Judge, he has an exhibit.  
16 THE COURT: Just one minute. You have a matter to --  
17 MR. SLATER: I forgot to move the exhibit.  
18 THE COURT: It may be admitted.  
19 MR. SLATER: P-2864.  
20 (PLAINTIFF'S EXHIBIT P-2864 WAS RECEIVED IN EVIDENCE.)  
21 (The Jury left the courtroom at 2:40 p.m.)  
22 THE COURT: I'll see you in 15 minutes.  
23 (A recess was taken at 2:40 p.m.)  
24 (The jury entered the courtroom at 2:55 p.m.)  
25 THE COURT: On that "please be seated" business if at

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1 any time you want to stand up and stretch and so forth, feel  
2 free to do that. You don't need to stay glued to your chairs.  
3 MR. SLATER: Your Honor, it's going to be Dr. Carol  
4 DeHasse. We're just fixing one thing on the computer.  
5 THE COURT: All right. The next witness is another  
6 video witness. I believe this is the treating physician.  
7 MR. ANDERSON: That's correct, Your Honor.  
8 THE COURT: All right. Treat the testimony the same  
9 as you would any other testimony presented here in the  
10 courtroom.  
11 You may proceed.  
12 MR. AYLSTOCK: Just another minute, Your Honor. I  
13 apologize.  
14 THE COURT: Sure.  
15 MR. SLATER: I think something froze up and we just  
16 had to get the documents. I would tell a story about a duck  
17 but I don't know any.  
18 THE COURT: At least not any you can tell.  
19 MR. SLATER: No, that's true.  
20 THE COURT: I realize that we're working really hard  
21 to take short breaks and keep on trucking. But I've found out  
22 over 45 years of doing this that it's a lot easier just to run  
23 it on time and keep pressing forward than it is to drag it out  
24 over a month. So, at least that's my theory. I'm going to  
25 stick to it until somebody tells me different.

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1 (Pause)

2 MR. AYLSTOCK: Your Honor, it appears that we're

3 ready.

4 THE COURT: Here we go.

5 (The videotaped direct testimony of Carol Dehasse was

6 played from 3:02 p.m. until 3:51 p.m.)

7 MR. AYLSTOCK: Your Honor, that concludes the

8 plaintiff's presentation of Dr. Carol DeHasse. I have some

9 exhibits to move in.

10 THE COURT: All right. You may proceed.

11 MR. AYLSTOCK: Your Honor, I'd move into evidence for

12 the record Exhibit P-3404, Exhibit P-2103, Exhibit P-2105,

13 Exhibit P-3396, Exhibit P-1904, Exhibit P-1905, Exhibit

14 P-3405, Exhibit P-1906, Exhibit P-3400, Exhibit P-3401,

15 Exhibit P-2119, Exhibit P-3403, and Exhibit P-3393.

16 MR. THOMAS: I don't have all the ones you had,

17 Bryan. Can I see your stack?

18 MR. AYLSTOCK: Sure.

19 THE COURT: A couple of those have already been

20 admitted.

21 THE CLERK: That's fine.

22 MR. AYLSTOCK: That's okay. I know one of them was a

23 defense exhibit.

24 THE COURT: Before you leave this evening, could you

25 get me the deposition transcripts of the videos we've played

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1 MR. AYLSTOCK: Why don't you just read it, David.

2 MR. THOMAS: If I can go back, --

3 THE COURT: I'll need to explain this to the jury if

4 that's what you're going to do.

5 MR. THOMAS: Okay. The -- I'm sorry. I'm mistaken I

6 guess.

7 THE COURT: All right.

8 MR. THOMAS: I apologize, Your Honor.

9 THE COURT: Okay. Push play.

10 MR. THOMAS: It's in this one too, Your Honor. It is

11 an omission apparently. Do you mind if I just read it in?

12 THE COURT: No. Let me explain to the jury.

13 As I told you, and I know you understand by now, this

14 was all testimony taken earlier and we took out all the

15 lawyering and the judging and have given you edited

16 videotapes.

17 In that process, apparently we have edited out

18 something that we shouldn't have edited out. And instead of

19 going back and trying to find the snippet of tape with the

20 testimony, I am going to ask counsel to simply read the

21 questions that were posed to this witness and to read her

22 answers. And you are to consider that in the same way you

23 would as if she were testifying from the witness stand.

24 Do you understand?

25 (All jurors indicated an affirmative response.)

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1 so far and get them --

2 MR. SLATER: They're all being marked -- we assumed

3 the Court would want them marked.

4 THE COURT: Yes.

5 MR. SLATER: We're having that done so you'll have

6 them, Your Honor.

7 THE COURT: Okay.

8 MR. AYLSTOCK: Perhaps in the interest of expediency,

9 we can just deal with this at a sidebar.

10 MR. THOMAS: There are several I don't have. I just

11 need to make sure --

12 THE COURT: All right. The motion to admit will be

13 left pending.

14 MR. THOMAS: Thank you, Your Honor.

15 THE COURT: Is there cross?

16 MR. THOMAS: Yes, Your Honor, there is.

17 (The videotaped cross-examination testimony of Carol

18 DeHasse was played from 3:55 p.m. until 4:26 p.m.)

19 MR. THOMAS: Your Honor, could we stop for a minute,

20 please? May I confer with plaintiff's counsel, please?

21 THE COURT: Yes.

22 MR. THOMAS: Your Honor, there was a Q and A omitted

23 from the transcript.

24 THE COURT: Okay. How do you want to fix that? Do

25 you want to do a read?

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1 THE COURT: Are we in agreement, counsel?

2 MR. AYLSTOCK: We are, Your Honor. No objection.

3 THE COURT: You may proceed.

4 MR. THOMAS: With permission, I'd like to ask a

5 couple of questions ahead of time to put it in context. Is

6 that all right?

7 THE COURT: Yes.

8 MR. AYLSTOCK: Sure.

9 MR. THOMAS: Beginning at 463, line 25:

10 "She's just -- she's having some spotting, flashes,

11 difficulty sleeping, and mood lability.

12 Answer: Yes.

13 Question: Needs HRT.

14 Answer: Hormone replacement therapy.

15 Question: All right. Was it at this point you're

16 still prescribing the estrogen cream?

17 Answer: Yes.

18 Question: And that would have been important to use?

19 Answer: Yes."

20 That's all, Your Honor.

21 MR. AYLSTOCK: Thank you.

22 THE COURT: All right. Let's continue with the

23 video.

24 (The videotaped cross-examination testimony of Carol

25 DeHasse was resumed and played from 4:29 p.m. until 4:49 p.m.)

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1 MR. THOMAS: Your Honor, I've had a chance to review  
2 the exhibits tendered by plaintiff at the close of their  
3 evidence and we have no objection to the exhibits that they  
4 tendered.

5 Defendants offer Defendant's 10141, 10140, 10135, and  
6 10116 and ask that those be received into evidence.

7 MR. AYLSTOCK: I just haven't seen them, Your Honor.  
8 I'm sure it's fine.

9 MR. THOMAS: In addition, Your Honor, in the course  
10 of the examination of Dr. DeHasse, she identified and actually  
11 brought with her to the deposition a different patient  
12 brochure.

13 MR. AYLSTOCK: Your Honor, could we, could we do this  
14 at the sidebar? This is --

15 THE COURT: Yes.

16 MR. THOMAS: We can do it later if you like.

17 THE COURT: We can do it now.

18 MR. AYLSTOCK: There's no redirect.

19 MR. THOMAS: Okay, perhaps now.

20 THE COURT: Let's do it now.

21 (The following occurred at sidebar:)

22 THE COURT: All right, sir.

23 MR. THOMAS: Your Honor, during the deposition of Dr.  
24 DeHasse you heard testimony about the 2008 patient brochure  
25 that Dr. DeHasse brought with her to the deposition and she

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1 to say she had the 2006. But I didn't see anything where you  
2 asked this witness about the 2008 brochure or any discussion  
3 about it other than did she or did she not give it to her and  
4 she said she didn't know.

5 I'm sure in your case you may find a way to get the  
6 2008 brochure in, but I'm not going to let it in right now.

7 MR. AYLSTOCK: Thank you, Your Honor.

8 MR. THOMAS: Thank you, Your Honor.

9 (Sidebar concluded.)

10 THE COURT: Ladies and gentlemen, we're going to keep  
11 working. It's going to be about 13 minutes. We're going to  
12 keep working. You'll be glad.

13 MR. AYLSTOCK: Your Honor, the plaintiff's exhibits  
14 identified in conjunction with Dr. DeHasse, are those exhibits  
15 admitted?

16 THE COURT: They are.

17 MR. AYLSTOCK: Thank you, Your Honor.

18 THE COURT: As are the ones offered by the defendant  
19 just now.

20 (PLAINTIFF'S EXHIBITS P-3404, P-2103, P-2105, P-3396,  
21 P-1904, P-1905, P-3405, P-1906, P-3400, P-3401, P-2119,  
22 P-3403, and P-3393 RECEIVED IN EVIDENCE.)

23 (DEFENDANT'S EXHIBITS 10141, 10140, 10135, AND 10116  
24 RECEIVED IN EVIDENCE.)

25 THE COURT: Go ahead and start the television.

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1 was questioned about that. And the questions about it related  
2 to whether the 2008 brochure or the 2006 brochure was the one  
3 reviewed by the plaintiff in the case.

4 THE COURT: Uh-huh.

5 MR. THOMAS: And the testimony from the doctor is --  
6 although she brought it with her, she could not be sure which  
7 brochure that Ms. Bellew saw. And I think it's only fair for  
8 the jury to have the benefit of that brochure as they  
9 deliberate as well.

10 MR. AYLSTOCK: Your Honor, I don't believe that any  
11 testimony from Dr. DeHasse was designated or played about the  
12 2008 brochure. She was simply asked: Which one? Does she  
13 recall? And she said, no, she does not. The testimony in  
14 this case from Mrs. Bellew will be she saw the 2006 brochure  
15 and only the 2006 brochure. So, --

16 THE COURT: All right. Here's what I remember. She  
17 was asked and, by Ethicon's lawyer, "Isn't it more likely,  
18 given the time frame, that she was given the 2008 brochure?"

19 MR. THOMAS: Exactly right.

20 THE COURT: And she said, "Not necessarily. It just  
21 kind of depends. They just --" from an earlier answer she  
22 said, "They just add them to the stack." And without  
23 remembering the exact words, she said, "I just can't say which  
24 brochure she got."

25 Now, I know from reading the papers that she's going

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1 MR. SLATER: Okay, Your Honor.

2 Your Honor, through the mayhem, plaintiff calls Bryan  
3 Lisa who worked at Ethicon Regulatory Affairs during the  
4 relevant time period.

5 THE COURT: All right.

6 (The videotaped direct examination testimony of Bryan  
7 Lisa was played from 4:54 p.m. until 5:07 p.m.)

8 MR. AYLSTOCK: Your Honor, that concludes the  
9 testimony of Mr. Bryan Lisa.

10 THE COURT: I understand there's no cross.

11 MR. SLATER: There's no cross, Your Honor, and we  
12 have a few exhibits to move and we have those transcripts for  
13 you as well.

14 We move from this deposition P-160, P-0366, and  
15 P-0462, although I think we should confer. There may be a  
16 couple things that we may want to work on, some redactions I  
17 just noticed just in case.

18 MS. JONES: Your Honor, we would have objections to  
19 the P-462 and P-366 that we would need to take up.

20 THE COURT: All right. Why don't I let the jury go  
21 home and let's straighten this out.

22 MR. SLATER: No problem.

23 THE COURT: Ladies and gentlemen of the jury, we'll  
24 be in recess, be adjourned for the day and start again at 9:00  
25 in the morning. The roads are icy. So, if you live very far

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1 away, you probably ought to spend another night in the warmth  
2 of your hotel room. It's up to you entirely.

3 You are serving as jurors, a mandatory duty of  
4 citizenship, but I am not adding the additional condition that  
5 you be confined. So, it will be entirely up to your good  
6 judgment what you do. But I'll expect to see all your shining  
7 faces here tomorrow at 9:00. Have a nice evening.

8 Don't discuss the case or communicate about the case  
9 in any way, shape, or form.

10 (The jury left the courtroom at 5:09 p.m.)

11 THE COURT: Of course as you're rattling off those  
12 numbers, I have not the slightest idea what you're talking  
13 about. So, you're going to have to tie a number to a subject  
14 matter or I won't be able to figure it out.

15 MS. JONES: May I address our objections because I  
16 think it's fairly simple and Your Honor may wish to look at  
17 the documents?

18 I object to P-462 about which Mr. Lisa was  
19 questioned. Plaintiffs have identified some of it. But it  
20 is, in fact, a letter to the -- I'm sorry -- the redacted  
21 portions of it. It is, in fact, a letter to the FDA. It is  
22 strictly a regulatory document.

23 And under those circumstances and under Your Honor's  
24 rulings thus far, I think it would be inappropriate to be  
25 admitted.

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1 of pages would be, but I anticipate that it will all be  
2 ultimately.

3 THE COURT: That's fine.

4 MR. SLATER: Thank you.

5 THE COURT: It's got a number on it?

6 MR. SLATER: It does and it was utilized.

7 THE COURT: May be admitted.

8 (PLAINTIFF'S EXHIBIT P-1593 RECEIVED IN EVIDENCE.)

9 MR. SLATER: For the record, I could read in the  
10 exhibit numbers and we have the transcript excerpts for you,  
11 Your Honor, on all the deposition designations save I told --  
12 I looked around because we traded people, so Mr. Lisa's is  
13 being stamped right now. But I have them ready to read the  
14 numbers for you, Your Honor, and hand them up.

15 THE COURT: The deposition exhibits as played today  
16 is what you're going to present now?

17 MR. SLATER: These are the -- I have them all.

18 THE COURT: Or yesterday or all of the day.

19 MR. SLATER: These are all of the scripts for what  
20 was actually played to the jury, Your Honor.

21 MS. JONES: By the plaintiffs or by --

22 MR. SLATER: By the plaintiffs.

23 MR. AYLSTOCK: And I have a courtesy copy for Your  
24 Honor if you'd like them.

25 THE COURT: Okay. They're not exhibits. They're

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1 THE COURT: I had some problem with the testimony.

2 MS. JONES: Well, so did I.

3 THE COURT: But it's -- I adopted the rulings. I'll  
4 look at that.

5 MS. JONES: The second thing, Your Honor, is a  
6 similar document, P-366, which is also a regulatory document.  
7 It is addressed "To Whom It May Concern" but it's provided  
8 that it can be released to the following countries. And, so,  
9 it actually is a foreign regulatory document that --

10 THE COURT: Can I -- let's go off the record so I can  
11 ask a few silly questions.

12 (Discussion off the record after which the following  
13 occurred:)

14 MS. JONES: I have no objection to 160.

15 THE COURT: 160 is received.

16 (PLAINTIFF'S EXHIBIT P-160 RECEIVED IN EVIDENCE.)

17 MR. SLATER: I also have with Dr. Elliott and we  
18 referenced it several times -- I thought I had moved it.  
19 Apparently I may not have. It's P-1593. It's a document --  
20 the professional education dec used at the time Dr. DeHasse  
21 said she was trained. We offer that into evidence. It's  
22 already been utilized in the testimony with Dr. Elliott  
23 several times.

24 MS. JONES: I don't have any objection. I think  
25 that -- my recollection was that we had agreed that a couple

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1 filed.

2 MR. SLATER: They're filed. Okay. Shall I identify  
3 them for the record?

4 THE COURT: Yes, please.

5 MR. SLATER: Okay. I'll go through them real quick.

6 Paul Parisi, P-3414; Piet Hinoul, P-3415; Uwe Klinge,  
7 P-3416; Gene Kammerer, P-3417; Vincent Lucente, P-3418; Scott  
8 Ciarrocca -- that's C-i-a-r-r-o-c-c-a -- P-3419; Sean O'Bryan,  
9 P-3420; Charlotte Owens, P-3421; Kimberly Hunsicker, P-3422;  
10 Dr. Carol DeHasse, P-3423; Bryan Lisa, P-3425.

11 They're now identified and I have them here for the  
12 Court.

13 And my last piece of housekeeping is -- whether it  
14 has to be on the record -- this is probably not an  
15 on-the-record kind of thing.

16 THE COURT: Okay. These may be filed as exhibits and  
17 considered a part of the transcript of the proceedings.

18 MR. SLATER: Thank you, Your Honor.

19 The only other issue I was going to state, counsel  
20 asked when we thought we were going to rest based on where we  
21 are. We have to look at the timing of how we did today. But  
22 we think -- counsel -- based on -- this doesn't have to be for  
23 the record frankly. It's up to you.

24 THE COURT: No.

25 (Discussion off the record, after which the following

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1 occurred:)

2 MR. THOMAS: Your Honor, we filed, pursuant to the  
3 Court's direction, some modifications to the Pre-Trial Order  
4 and to the jury instructions.

5 THE COURT: All right. Anybody else got anything  
6 like that?

7 MR. ANDERSON: Real quickly, Your Honor, just that  
8 Your Honor had earlier -- we admitted Plaintiff's Exhibit 1910  
9 during Dr. Iakovlev, but it was subject to, it was subject to  
10 just pulling out the particular exhibits that did not have  
11 writing on them.

12 And, so, I've met with Mr. Thomas and we've pulled  
13 out which ones of those are going to go into the record. That  
14 would be Plaintiff's Exhibit 1910-Z. That would be  
15 Plaintiff's Exhibit 1910-NN. That would be Plaintiff's  
16 Exhibit 1910-BBB. That would be Plaintiff's Exhibit 1910-ZZ.  
17 That would be Plaintiff's Exhibit 1910-L. Plaintiff's Exhibit  
18 1910-CC, but we have the version that's marked. And, so,  
19 we're going to bring you the one tomorrow morning that doesn't  
20 have the marking on it. It's the exact same photo and it's  
21 one that we put on the record at the very end. But I will  
22 replace that for you tomorrow. Would you like it for now and  
23 then I replace it or I just keep it?

24 THE CLERK: Sure. That's fine.

25 MR. ANDERSON: All right. And I believe that covers

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1 adequate warnings to the doctor that the learned intermediary  
2 defense is gone from the case. And we would -- we're going to  
3 hope to convince Your Honor that an instruction could be  
4 fashioned that would be contingent on that finding because I  
5 know Your Honor relied on the learned intermediary to say  
6 there would not be fraud. But we believe that if the jury  
7 finds failure to warn because there's a lack of adequate  
8 warnings, there is by law in Arizona no learned intermediary  
9 defense at that point because it's obviously phrased as if an  
10 adequate warning is provided to the doctor, then you don't  
11 have to warn the plaintiff.

12 But if they haven't adequately warned the doctor,  
13 then they would have had the duty to provide accurate  
14 information. They would no longer have that defense anymore,  
15 and then fraud would be in play at that point. That's our  
16 position.

17 MR. AYLSTOCK: Your Honor, -- I'm sorry, Your Honor.  
18 This is Eric Walker. He's writing a responsive brief, so I  
19 just wanted to introduce him to Your Honor.

20 MR. WALKER: One of the briefs that Mr. Aylstock  
21 referenced is a very short brief we're filing. An Arizona  
22 Court of Appeals ruled this year, just a couple months ago,  
23 that the learned intermediary doctrine does not apply in  
24 Arizona anymore.

25 THE COURT: I read it yesterday afternoon.

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1 that bit of housekeeping. I ask it be admitted.

2 THE COURT: May be done.

3 MR. ANDERSON: Thank you, Your Honor.

4 (PLAINTIFF'S EXHIBITS 1910-Z, 1910-NN, 1910-BBB,  
5 1910-ZZ, 1910-L, 1910-CC RECEIVED IN EVIDENCE.)

6 MR. AYLSTOCK: This doesn't need to be on the record.

7 (Discussion off the record, after which the following  
8 occurred:)

9 MR. ANDERSON: I'm so sorry. I missed one.

10 David, I missed one. It was the 1910-PP.

11 MR. THOMAS: No objection.

12 MR. ANDERSON: I ask that it be admitted, Your Honor.

13 THE COURT: May be admitted.

14 MR. THOMAS: No objection, Your Honor.

15 (PLAINTIFF'S EXHIBIT 1910-PP RECEIVED IN EVIDENCE.)

16 MR. ANDERSON: Thank you.

17 THE COURT: Let's stay on the record for a minute.

18 You still are talking in your papers filed, the  
19 plaintiffs, about fraud and misrepresentation. Those claims  
20 were dismissed.

21 MR. AYLSTOCK: Your Honor, --

22 MR. SLATER: The reason -- if I may, Your Honor.

23 THE COURT: Sure.

24 MR. SLATER: As I had stated at sidebar the other  
25 day, we believe that if the jury finds that there were no

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1 MR. WALKER: And, so, we're filing a supplemental  
2 brief on that. It's very short.

3 THE COURT: Okay. I'm well aware of that case.

4 MR. AYLSTOCK: Thank you, Your Honor.

5 THE COURT: You might also address, while you're at  
6 it, if there's anything in that case that changes the, in your  
7 opinion, the law of punitive damages in Arizona. Oh, we're  
8 going with New Jersey law in this case. Nevermind. I don't  
9 care what the punitive damage law is in Arizona.

10 MR. ANDERSON: As you were saying. Right?

11 THE COURT: Yeah. Go ahead and give them that cite  
12 now so they can give any response they want to give instead of  
13 waiting until the midnight brief. I've read that case and we  
14 did a little work on it yesterday. So, I'm aware of it.  
15 Actually, it's why I asked whether or not anybody was going to  
16 file any additional things.

17 See you later.

18 MR. ANDERSON: Thank you, Judge.

19 MR. AYLSTOCK: Thank you, Your Honor.

20 MR. SLATER: Thank you, Your Honor.

21 MS. JONES: Thank you, Your Honor.

22 (Trial recessed at 5:27 p.m.)

23 - - - - -

24

25



## REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RSA, RPR, and Lisa A. Cook,  
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Virginia, do hereby certify that the foregoing is a true and  
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/S/ Carol Farrell, CRR, RMR, CCP, RSA, RPR 03/05/2015

\_\_\_\_\_  
Court Reporter Date

/S/ Lisa A. Cook, RPR, RMR, CRR, FCRR 03/05/2015

\_\_\_\_\_  
Court Reporter Date

# EXHIBIT S

## ORIGINAL ARTICLE

P. Bracco · V. Brunella · L. Trossarelli · A. Coda  
F. Botto-Micca**Comparison of polypropylene and polyethylene terephthalate (Dacron) meshes for abdominal wall hernia repair: A chemical and morphological study**Received: 12 March 2004 / Accepted: 26 July 2004 / Published online: 10 September 2004  
© Springer Verlag 2004

**Abstract** For the first time, by scanning electron microscopy (SEM), polypropylene (PP) excised meshes (ethylene oxide sterilized) for abdominal wall hernia repair have been shown to be greatly damaged physically, independently of the implantation time, while the polyethylene terephthalate (PET), or Dacron, ones (gamma radiation sterilized), did not undergo alterations due to the sterilization process and were not damaged, even after long implantation periods. Fourier-Transform Infrared Spectroscopy (FTIR) study of PP and PET excised meshes, as well as of their extracts with cyclohexane, has shown the presence of species, such as squalene, palmitic and stearic acid, in some cases, cholesterol, transferred from the surrounding tissues to the polymer during the implantation period. In the case of PP meshes, these small organic molecules would reduce physical and mechanical properties of the material. A hypothesis is presented to account for the better behavior (not in the clinical sense) of PET meshes.

**Keywords** Polymeric meshes · Abdominal wall hernia · Scanning electron microscopy · Infrared spectroscopy

**Introduction**

In the literature, there are only a few investigations of modifications undergone by meshes [1] after

implantation, mainly carried out on animals [2] or by x-ray in vivo [3], but, as far as we know, only our group [4] reported modifications of polymeric meshes after long periods in the human body.

In previous papers, we have reported modifications undergone by certain polymeric materials for medical use, arising both from the sterilization process, when carried out with high-energy radiations [5, 6], and from their stay in the human body [7].

The subject of the present paper is an investigation by scanning electron microscopy (SEM), infrared (IR) spectroscopy, and gas chromatography (GC) on polyethyleneterephthalate, or Dacron, (PET) and polypropylene (PP) meshes for abdominal wall hernia repair. The aim was to verify for Dacron (PET) meshes, which were gamma sterilized by the manufacturer, if this sterilization process had given rise to some physical damage and had modified their chemical structure (PP meshes were ethylene oxide sterilized by the manufacturer) and for both PET and PP meshes to discover the effect on their structure, due to the stay for long periods in the human body. The results obtained so far are presented and discussed herein.

**Materials and methods****Meshes**

During a 6-year period (1996–2002), at the Surgical Division of the Gradenigo Hospital in Turin, Italy, biopsies were performed on hernia meshes of 25 patients (24 male, 1 female), with a mean age of 62 years (range 37–89). The average period of implant was 32.5 months (range 2–180). All 25 fragments, from different manufacturers (Table 1), were excised during surgery not programmed nor carried out with this purpose. Polypropylene (PP) fragments were from PP meshes, which were ethylene oxide sterilized at the origin by the manufacturer, while the Dacron (PET) ones were from PET meshes sterilized at the origin with gamma radiations by

P. Bracco · V. Brunella (✉) · L. Trossarelli  
Dipartimento di Chimica IFM dell'Università di Torino,  
Via Pietro Giuria 7, 10125 Torino, Italy  
E mail: valentina.brunella@unito.it  
Tel.: +39 0116707546  
Fax: +39 0116707855

A. Coda  
Presidio Sanitario "Gradenigo", U.O.A. di Chirurgia Generale,  
Corso Regina Margherita 8, 10153 Torino, Italy

F. Botto Micca  
Presidio Sanitario "Gradenigo", Servizio di Anatomia Patologica,  
Corso Regina Margherita 8, 10153 Torino, Italy

**Table 1** Excised meshes

Sample	Sex	Age (years)	Polymeric material	Implantation time (months)
1	M	73	PP	16
2	M	58	PP	13
3	M	37	PP	9
4	M	89	PP	2
5	M	48	PP	8
6	M	67	PP	6
7	M	74	PP	7
8	M	37	PP	9
9	M	58	PP	12
10	M	70	PP	14
11	M	62	PP	34
12	M	64	PP	35
13	M	45	PP	36
14	M	71	PP	47
15	M	78	PP	11
16	M	70	PP	15
17	M	54	PP	24
18	M	59	PP	32
19	M	76	PP	36
20	M	53	PP	45
21	M	53	PP	52
22	F	65	PET	36
23	M	65	PET	96
24	M	69	PET	180
25			PET	36

PP = polypropylene; PET = polyethylene terephthalate

the manufacturer. After biopsy, either PET or PP mesh fragments were fixed in 4% formalin. In order to eliminate any organic residue, the fragments were treated for 24 h with a NaClO solution (Fluka 6–14% active chlorine) at 37°C and washed with distilled water. When fragments 4 cm<sup>2</sup> or larger (PRO\_36, PRO\_47, TRE\_11, TRE\_32, and LI\_96) were available, they were extracted for 24 h with boiling cyclohexane. Cyclohexane was removed with a rotating evaporator and the residue recovered with a few drops of cyclohexane.

### Scanning electron microscopy

A Leica Stereoscan 420 SEM equipped with a secondary electron detector was used. The samples were previously coated with gold in a Bio Rad, Polarum Division, E 5000 M SEM Coater (120 s at 18 mA).

### Infrared spectroscopy

An FT-IR Perkin Elmer AutoImage microscope, with an MCT detector, enabling sampling on surfaces down to 10×10 μm, which can operate both in transmission and in reflection and equipped with a Micro-ATR system, was used. Transmission spectra (resolution 4 cm<sup>-1</sup>, 32 scans per spectrum) were collected on a 100×100 μm surface area.

IR spectra of cyclohexane extracts were registered (32 scans per spectrum) with an FT-IR Perkin Elmer System

2000 with a resolution of 4 cm<sup>-1</sup> from films supported on KBr discs.

### Gas chromatography

An Agilent 6890 gas chromatograph with a FID detector was used, carrier gas He (2 ml/min), equipped with a 10 m capillary column Rtx-5MS, 0.32 mm internal diameter, coated with a 0.1 mm layer of 5% phenyl-95% methylarylene polysiloxane, temperature program 20°C/min from 60°C up to 200°C and then 5°C/min up to 360°C.

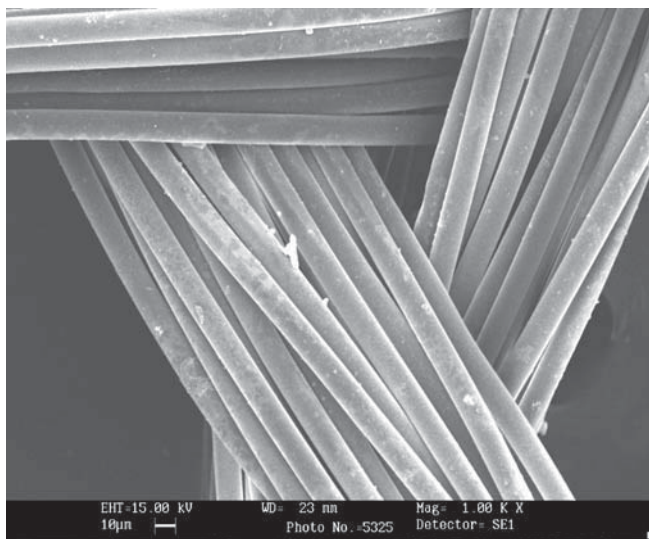
Stearic acid, palmitic acid, squalene, cholesterol, cholesteryl stearate, and cholesteryl palmitate (Fluka, purity > 99%) were used as standards.

## Results

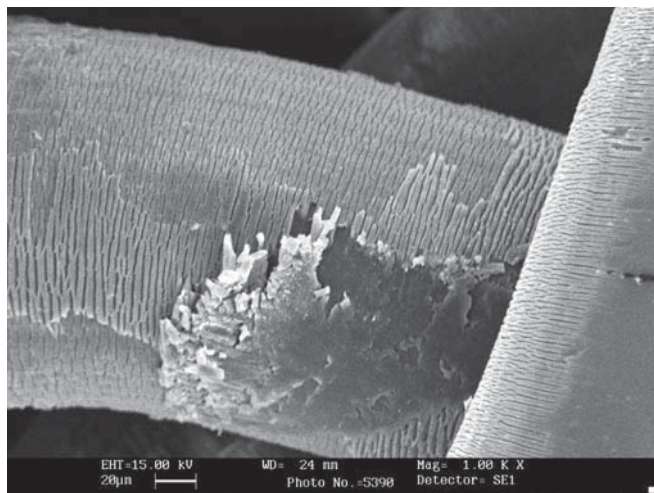
Virgin PET and PP meshes by the same manufacturers of the fragments listed in Table 1, treated in the same manner as the excised ones, were preliminarily studied to see if formalin and NaClO treatments had chemically modified the materials. The IR spectra of virgin PET and PP meshes, before and after the treatment with formalin and then with NaClO, are, respectively, the typical IR spectra of PET and of PP without any additive reported in the literature.

In the SEM image of fragment #24 (PET) (Fig. 1) excised after a 180-month stay in the human body, taken as representative of all the other PET excised mesh fragments listed in Table 1, no defects nor any damage were detectable.

Two SEM images of PP excised mesh fragments were taken as representative of all the other PP excised mesh fragments listed in Table 1 (Fig. 2, and Fig. 3).



**Fig. 1** Scanning electron microscopy (SEM) micrograph (1,000×) of fragment #24 polyethylene terephthalate (PET)

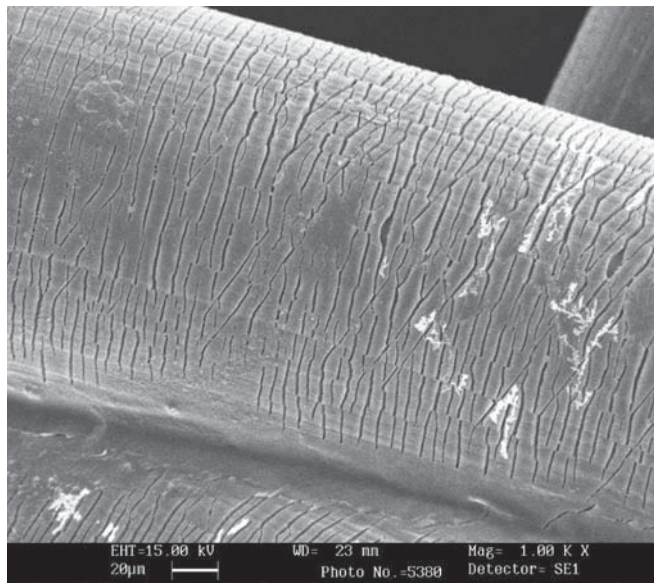


**Fig. 2** Scanning electron microscopy (SEM) micrograph (1,000×) of fragment #20 polypropylene (PP)

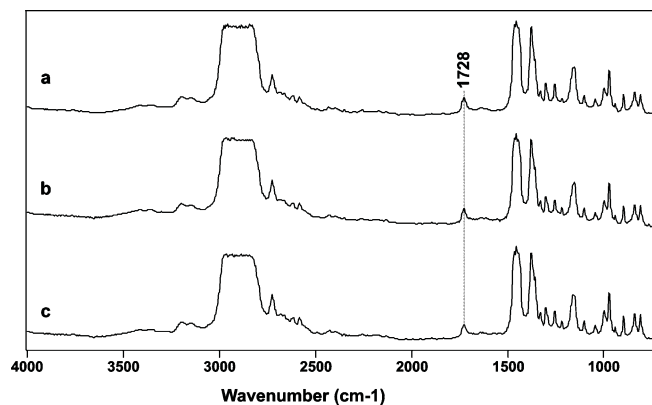
In Fig. 4, some representative IR spectra of excised PP mesh fragments listed in Table 1 are collected. Common to all these IR spectra is the new absorption band in the C=O region at  $1,728\text{ cm}^{-1}$ .

In Fig. 5 are reported the IR spectra of sample #13 (PP) before and after extraction with cyclohexane, taken as representative of all the other PP samples listed in Table 1; it can be observed that the absorption band at  $1,728\text{ cm}^{-1}$  practically disappears after cyclohexane extraction.

In Fig. 6, the IR spectrum of the extract with cyclohexane of sample #15 (PP) is reported as an example. Quite similar IR spectra have been obtained for samples #14, #13, and #18 and for sample #23 (PET) listed in Table 1.



**Fig. 3** Scanning electron microscopy (SEM) micrograph (1,000×) of fragment #9 polypropylene (PP)

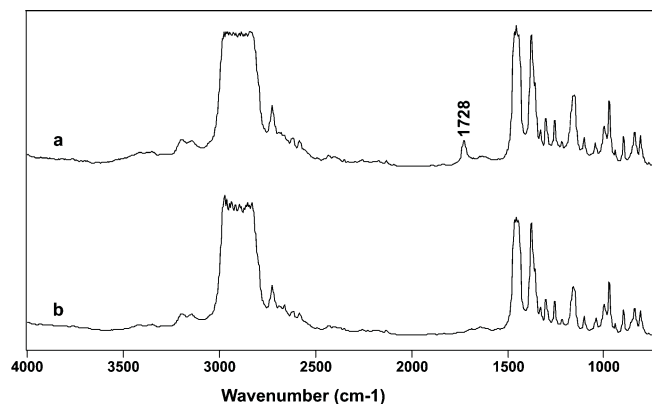


**Fig. 4** Fourier Transform Infrared Spectroscopy (FTIR) spectra of fragments **a** #9, **b** #14, **c** #13

The gas chromatograms of the cyclohexane extracts of samples #13, #14 (both PP), and #23 (PET) are similar, and so only the GC of sample #13 has been reported (Fig. 7).

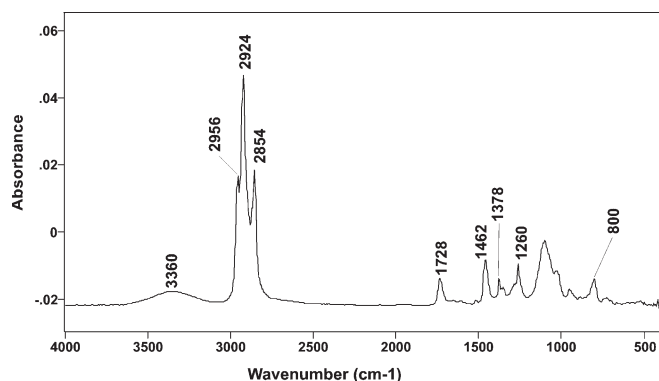
## Discussion

The IR spectra of both virgin PET and PP meshes and virgin PET and PP meshes treated with formalin and NaClO show that within the sensibility of our instrument, neither of these reagents modified the chemical structure of the materials. Since the IR spectra of PET and PP meshes do not differ from those reported in the literature for PET and PP without additives, this means that processing did not alter the chemical properties of either material; it also did not alter PP meshes sterilized with EtO. For PET meshes, it should be pointed out that gamma-radiation sterilization did not affect the chemical structure of the polymer, in agreement with what is commonly observed for polymeric materials with aromatic rings when treated with high-energy radiations [8]. SEM images of both virgin PET and PP meshes before



**Fig. 5** Fourier Transform Infrared Spectroscopy (FTIR) spectra of fragment #13 **a** before and **b** after cyclohexane extraction





**Fig. 6** Fourier Transform Infrared Spectroscopy (FTIR) spectrum of the cyclohexane extract of fragment #15

and after the treatment with formalin and then with NaClO do not show defects or physical damages, and this means that both these treatments, as well as sterilization with gamma radiation in the case of PET meshes, did not physically modify the fibers.

As previously pointed out, the SEM image of a PET mesh fragment excised after a 180-month stay in the human body (Fig. 1) does not show defects or damage of any kind. Because of the very small sizes of the fragments of excised PET meshes under investigation, we have not been able to investigate whether alterations of molecular weight, molecular weight distribution, crystallinity, and mechanical properties occurred as a consequence of their stay in the human body, as reported in the literature in the case of excised PET arterial prostheses [9, 10]

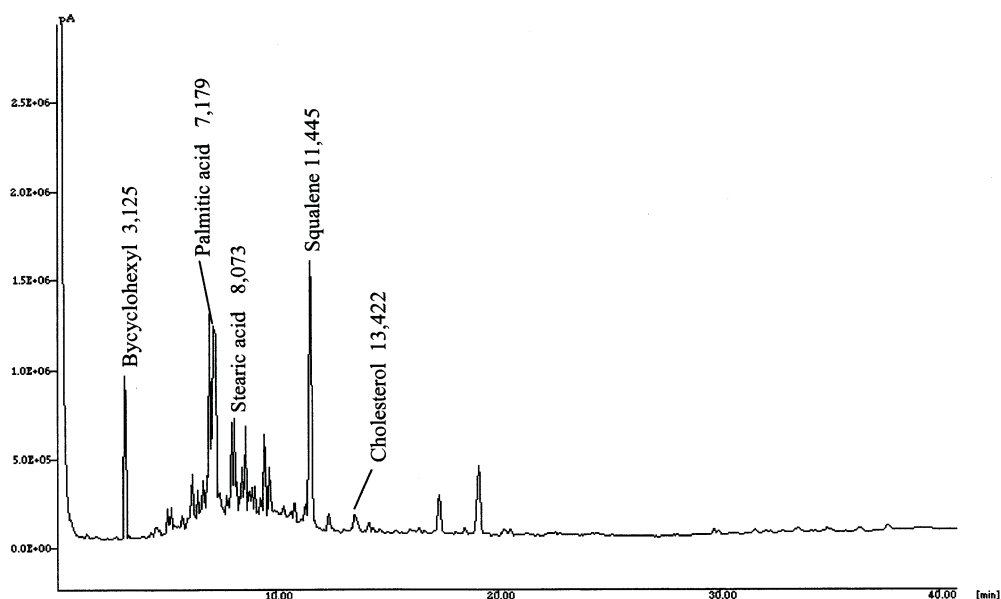
In all the PP excised mesh fragments listed in Table 1 (Fig. 2 and Fig. 3), independently of the manufacturer or the implantation time, the filaments appear badly

damaged. This seems to be in disagreement with what is clinically observed [11, 12], namely that PP meshes give an inflammatory response and an extraneous body reaction less than the PET ones. A possible explanation of this clinical observation could be a better integration of PP meshes than that of the PET ones with the surrounding tissues.

In the IR spectra of Fig. 4 the lack of absorptions in the regions of CONH groups ( $3,300$ ,  $1,600$   $\text{cm}^{-1}$ ) means that the treatment with NaClO has completely removed all tissues adherent to excised mesh fragments. Common to all the IR spectra of excised PP mesh fragments listed in Table 1 is a new absorption band in the C=O region at  $1,728$   $\text{cm}^{-1}$ , which is not detectable in the IR spectra of PET excised mesh fragments, being completely overlapped by that of the terephthalic ester. This new absorption band practically disappears (Fig. 5) after cyclohexane extraction, and this emphasizes that it does not arise from a chemical modification of PP due to its stay in the human body, but it arises from chemical species present in the human tissues that have been transferred to the polymer.

IR spectrum of the cyclohexane extract of a PET excised mesh fragment is totally similar to those of the PP ones; this observation confirms the previous hypothesis of the lack of the absorption band at  $1,728$   $\text{cm}^{-1}$  in the excised PET mesh IR spectra. Moreover, the close similarity between the IR spectra of the extracts from PP and PET excised mesh fragments illustrates that gamma sterilization of PET meshes did not alter the chemical structure of the polymer. The absorption at  $3,360$   $\text{cm}^{-1}$  in the IR spectrum of a typical cyclohexane extract could be attributed to the stretching of alcoholic OH and those at  $2,956$  and  $2,871$   $\text{cm}^{-1}$ , at  $2,924$  and  $2,854$   $\text{cm}^{-1}$ , and at  $1,462$  and  $1,378$   $\text{cm}^{-1}$  could be attributed to  $\text{CH}_3$

**Fig. 7** Gas chromatogram of the cyclohexane extract of fragment #13



and to CH<sub>2</sub> stretching and to CH<sub>2</sub> and CH<sub>3</sub> bending, respectively. The absorption band at 1,728 cm<sup>-1</sup> could be attributed to the C=O stretching of an ester group [13]. Since the ratio 1,728/1,462 is small, this would indicate the presence in the extract of high molecular mass esters.

All gas chromatograms show that in addition to some species, which at the present we have not been able to identify, there is always squalene and palmitic acid, while cholesterol and its derivatives and stearic acid are not present in all the extracts. Squalene and cholesterol in the extracts have been confirmed by gas chromatography-mass spectroscopy, and it should be pointed out that squalene is one of the precursors of cholesterol [14], and so it is always present in organic tissues.

In regard to the extracted products from excised PET and PP mesh fragments, the situation seems to be in some way similar to that already reported by some of us in the case of the products extracted from excised Ultra High Molecular Weight Polyethylene (UHMWPE) hip prostheses, where, in addition to fatty acids, squalene and cholesterol, cholesteryl esters of fatty acids as well were found [15]. IR spectra of the cyclohexane extracts of excised mesh fragments indeed show the presence of some high molecular weight esters, as suggested by IR spectra, for instance triglycerides, which probably cannot be eluted under our gas chromatography operating conditions. Triglycerides, such as tristearine and tripalmitine, which show IR absorption bands in the 1,730 cm<sup>-1</sup> region, in fact are not eluted under our experimental conditions. Both the composition and the relative concentration of each substance in the extracts from excised PET and PP mesh fragments seem to vary slightly depending on the individual patient, as was already found in the case of the UHMWPE hip prostheses [15].

Diffusion into mesh filaments of the small organic molecules mentioned above could be responsible for the damage observed on PP mesh filaments, since the presence of small foreign molecules could greatly affect their physical and mechanical properties. It is well known that physical and mechanical properties of polymeric materials depend on intermolecular secondary bond forces (van der Waals-London forces) between polymeric chains and on possible hydrogen bonds. In the case of PP and of PET, the physical and mechanical properties of the first, a nonpolar polyhydrocarbon molecule, will essentially depend on van der Waals-London forces of the induced dipole type, while for the second, a polyester molecule with highly polar groups along the chain, van der Waals-London forces of the dipole-dipole type between carbonyl groups are also to be taken into account and the hypothesis of weak hydrogen bonds cannot a priori be refused. It should also be pointed out that the aromatic rings along the PET chains make them stiffer than the PP ones, and it is well known that chain stiffness greatly contributes to increased physical and mechanical properties of polymeric materials [16].

## Conclusions

According to the above considerations, one can conclude that the absorption of small organic molecules by mesh filaments could be the reason for part of the observed shrinkage of mesh pores [4, 7]. As a consequence of the better integration of PP meshes with the surrounding tissues than those of PET, they would be highly damaged during their stay in the human body. The better integration with surrounding tissues of PP meshes than those of PET could also be an explanation of their lower inflammatory response and lower extraneous body reaction as clinically observed [10, 12]. Work is in progress on this subject.

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# EXHIBIT T



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Human Tissues: Chemical Composition and Photon Dosimetry Data

Author(s): Young S. Kim

Source: *Radiation Research*, Vol. 57, No. 1 (Jan., 1974), pp. 38-45

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# Human Tissues: Chemical Composition and Photon Dosimetry Data

YOUNG S. KIM

*Physics Department, The Ohio State University, Columbus, Ohio 43210*

KIM, YOUNG S. Human Tissues: Chemical Compositions and Photon Dosimetry Data. *Radiat. Res.* 57, 38-45 (1974).

Chemical compositions of bone (femur), bone (rib), brain (whole), spinal cord, heart (whole, auricles, right and left ventricles), kidney, liver, lungs, muscle, ovaries, pancreas, spleen, and tongue are given for an average human adult. Photon mass attenuation coefficient  $\mu$  and mass energy absorption coefficient  $\mu_{en}$  for these tissues are given for photon energies ranging from 15 KeV to 2 MeV.

## INTRODUCTION

It is known that the chemical composition for striated muscle, commonly used to represent various human tissues, is not actually representative of all human tissues and that several tissues differ significantly in chemical composition from striated muscle (1-3). We present chemical compositions of various human tissues and some photon dosimetric data for these tissues in this paper.

Chemical compositions of human tissues are of importance in studying microdosimetric distributions in humans irradiated with radiation; although primary interactions of photons are nearly independent of the chemical composition at high energies (in the Compton region), secondary interactions which are primarily responsible for biological effects do depend on the chemical composition (4-7).

Chemical composition of human tissues are usually given in terms of biological molecules (e.g., protein, lipid, vitamins, etc.), and they are not readily amenable to dosimetric calculations. At the usual therapy-machine energies, molecular binding effects are negligible (6, 7), and one may represent human tissues by their atomic compositions (% wt by elements). Mean atomic compositions of various biological molecules are readily available (2, 3, 8), and the mean atomic compositions of human tissues may be calculated from these data.

Chemical compositions of human tissues depend in general on breed, diet, age, sex, health, etc., and they may vary appreciably (5-10%) among individual human beings. The composition figures given in this paper represent only the averages with estimated standard deviations of about 5-8%.

Our figures include only those elements which constitute at least 0.1% (fractional weight) of the tissues. In the energy range considered in this paper (i.e., 15 KeV-2 MeV), a trace of any element less than 0.1% has negligible effects in



dosimetric considerations (1). It should be noted that due to rounding errors and other uncertainties, our composition figures do not always add up to unity.

### CHEMICAL COMPOSITIONS

Our basic composition data were taken from the following three sources: (a) *Biochemists' Handbook* (2), (b) *Handbook of Biological Data* (3), and (c) *Handbook of Chemistry and Physics* (8). Some pertinent data on the basic compositions are given below. Table I gives our results.

The composition of bone (femur) was taken to be 34% water, 18% femur protein, and other traces of elements as shown in Table I. The chemical composition of femur protein is given in Table II. These data were taken from (2). The chemical composition of rib bone was taken to be 71% water and the rest as shown in the table (3).

The composition of whole brain was taken to be 59% water, 10.4% lipids, 10.5% protein, 3.5% cholesterol, and traces of elements as shown in Table I. The brain protein composition was taken to be identical to that of pancreas protein given in Table III (2), and the chemical formula of cholesterol is given by  $C_{27}H_{45}OH$  (8). The composition of spinal cord was taken to be 60.9% water, 9.5% protein, 26.6% lipid, and traces of elements as shown in Table I. The lipid composition is assumed to be 11.2% H, 57.3% C, 1.1% N, 30.3% O, and 0.06% S.

The composition of whole heart was taken to be 75.5% water, 16% protein, 8.3% lipids, and other elements as shown in Table I; similarly, auricles (82% water, 16% protein), left ventricle (80% water, 16% protein, 0.8% lipids), and right ventricle (80% water, 16% protein, 2% lipids).

The two main biological components of kidney are water (78.5%) and protein (18%); in addition, kidney contains lipid (5.3%), DNA (0.036%), and traces of other elements (2). Concentrations of K and lipid are somewhat higher in cortex, while the water content and NaCl concentrations are higher in medulla.

The liver composition is subject to large uncertainties due to the fact that liver undergoes rapid changes in size and protein (glycogen in particular) metabolism. The water content, a multiple of the glycogen content, is also subject to rapid changes. We assumed that liver consists of 75% water, 17% protein, 6% lipid, and some other elements as given in Table I.

The lung composition was taken to be 79% water, 15% protein, 3% lipid, and some other elements (3). For lean somatic muscle, we assumed 75% water, 20% protein, and traces of other elements (2, 3). The composition of the ovary is for a nonpregnant woman, and it was taken to be 78.5% water, 6% protein, 0.16% cholesterol, 0.03% ascorbic acid, and 0.012% inositol (2).

The pancreas is made of essentially two components: water (85%) and protein (15%). The composition of pancreas protein is given in Table III (2). A second composition is given for the pancreas in (2), i.e., 66% water, 9.1% lipid, 22.7% protein, 3.7% N, and 0.6% P. Figures given in Table I reflect the first composition.

The spleen is made of three biological components—78.5% water, 17.5% protein, and 3% lipid (3), and the tongue is made of 64% water, 20% lipid, and 18% protein (2).

TABLE I  
CHEMICAL COMPOSITIONS OF VARIOUS HUMAN TISSUES

Tissue name	% Body wt <sup>a</sup>	H	C	N	O	Na	P	Cl	K	Others
Bone (femur)	15.0	0.056	0.093	0.033	0.0394	0.004	0.134	—	0.002	0.280 (Ca); 0.004 (Mg)
(rib)										
Brain (whole)	1.96	0.078	—	0.050	0.617	—	—	—	0.005	0.002 (Mg); 0.250 (Ca)
spinal cord	—	0.091	0.140	0.034	0.595	0.002	0.003	—	0.003	0.089 (Fe); 0.041 (Cu)
Heart (whole)	0.42	0.106	0.192	0.037	0.065	0.002	0.006	0.002	0.004	0.001 (S)
auricles	—	0.106	0.124	0.025	0.744	—	—	—	—	0.002 (S)
right ventricle	—	0.106	0.051	0.025	0.817	—	—	—	—	0.002 (S)
left ventricle	—	0.105	0.060	0.025	0.809	—	—	—	—	0.002 (S)
Kidney	0.41	0.106	0.055	0.025	0.813	—	—	—	—	0.002 (S)
Liver	2.30	0.091	0.029	0.116	0.692	0.019	0.015	0.019	0.019	—
Lungs	0.73	0.110	0.041	0.012	0.825	—	—	0.012	—	—
Muscle (lean somatic)	42.8	0.105	0.095	0.025	0.766	—	0.007	—	—	0.002 (S)
Ovaries	0.01	0.103	0.099	0.032	0.757	0.001	0.002	0.001	0.003	0.003 (S)
Pancreas	0.164	0.109	0.046	0.011	0.834	—	—	—	—	—
Spleen	0.25	0.107	0.072	0.023	0.800	—	—	—	—	0.002 (S)
Tongue	—	0.105	0.101	0.027	0.765	—	—	—	—	0.002 (S)
		0.107	0.173	0.031	0.683	—	0.002	—	—	0.003 (S)

<sup>a</sup> This column gives the percent weight of the tissues per adult human (average), and the other columns give the fractional weight of the elements per tissue.

TABLE II  
CHEMICAL COMPOSITION OF HUMAN BONE (FEMUR) PROTEIN

<i>Component</i>	<i>%</i>	<i>H</i>	<i>C</i>	<i>N</i>	<i>O</i>	<i>S</i>
Glycine	19.6	1.32	7.26	3.66	8.36	
Valine	2.52	0.24	1.29	0.3	0.69	
Leucine/isoleucine	4.73	0.47	2.60	0.51	1.15	
Proline	12.9	1.02	6.73	3.59	1.57	
Phenylalanine	2.22	0.15	1.45	0.19	0.43	
Tyrosine	0.77	0.05	0.46	0.06	0.20	
Serine	3.37	0.23	1.16	0.45	1.54	
Threonine	2.00	0.15	0.81	0.24	0.81	
Methionine	0.74	0.06	0.30	0.07	0.16	0.16
Arginine	7.90	0.64	3.27	2.54	1.45	
Histidine	0.85	0.05	0.39	0.23	0.18	
Lysine	3.86	0.37	1.90	0.74	0.85	
Aspartic acid	5.80	0.31	2.09	0.61	2.79	
Glutamic	10.00	0.62	4.08	0.95	4.35	
Hydroxyproline	12.20	0.84	5.59	1.30	4.47	
Hydroxylysine	0.55	0.05	0.24	0.10	0.16	
Alanine	8.70	0.59	3.52	1.37	3.13	
Total:		7.14	42.16	16.89	32.27	0.16

TABLE III  
CHEMICAL COMPOSITION OF HUMAN PANCREAS PROTEIN

<i>Component</i>	<i>%</i>	<i>H</i>	<i>C</i>	<i>N</i>	<i>O</i>	<i>S</i>
Aspartic acid	6.80	0.36	2.46	0.72	3.27	
Glutamic	13.70	0.85	5.59	1.30	5.96	
Lysine	8.1	0.78	3.99	1.55	1.77	
Arginine	5.0	0.41	2.07	1.16	0.92	
Histidine	3.7	0.22	1.72	1.00	0.76	
Tyrosine	2.6	0.16	1.55	0.20	0.69	
Tryptophan	2.4	0.14	1.55	0.33	0.38	
Phenylalanine	7.5	0.50	4.91	0.64	1.45	
Hydroxyproline	0.2	0.01	0.09	0.02	0.07	
Proline	6.8	0.54	3.55	1.89	0.83	
Cysteine	3.1	0.16	0.93	0.36	0.83	0.83
Methionine	2.1	0.16	0.85	0.20	0.45	0.45
Leucine/isoleucine	11.0	1.10	6.04	1.18	2.69	
Valine	8.1	0.77	4.16	0.96	2.21	
Glycine	4.3	0.29	1.38	0.80	1.84	
Alanine	6.7	0.46	2.71	1.05	2.41	
Serine	6.2	0.42	2.13	0.83	2.83	
Threonine	5.0	0.38	2.02	0.59	2.02	
Total		7.68	47.68	15.23	31.37	1.28

TABLE IV  
COMPARISON WITH PREVIOUS RESULTS

<i>Tissue</i>	<i>Reference</i>	<i>H</i>	<i>C</i>	<i>N</i>	<i>O</i>	<i>Na</i>	<i>P</i>	<i>Cl</i>	<i>K</i>	<i>Ca</i>	<i>Mg</i>	<i>S</i>
Muscle	This work	0.103	0.099	0.032	0.757	0.001	0.002	0.001	0.003	—	—	0.003
	Tipton-Cook (9)	0.100	0.11	0.026	0.75	—	0.002	0.002	0.003	—	—	—
	ICRU (10)	0.102	0.123	0.035	0.729	0.001	0.002	—	0.003	—	—	0.005
	Lea (11)	0.10	0.12	0.04	0.73	0.001	0.002	0.001	0.004	—	—	0.002
Bone	This work	0.056	0.093	0.033	0.394	0.004	0.134	—	0.002	0.280	0.004	—
	Tipton-Cook (9)	0.073	0.28	0.029	0.32	—	0.07	0.001	0.002	—	0.001	—
	ICRU (10)	0.064	0.278	0.027	0.41	—	0.07	—	—	0.147	0.002	0.002
	Jayachandran (11)	0.034	0.155	0.04	0.441	—	0.102	—	—	0.222	0.002	0.003

Our results for muscle and bone (femur) are compared with those of other workers in Table IV. In view of the large uncertainties involved in these types of figures, it may be stated that the composition data for *lean somatic muscle* (this paper), *soft tissue* (9), *striated muscle* (10), and *wet tissue* (11) are in an

TABLE V  
PHOTON MASS ATTENUATION AND MASS ENERGY ABSORPTION COEFFICIENTS (cm<sup>2</sup>/g)

<i>E</i> (MeV)	<i>Bone (femur)</i>		<i>Brain (whole)</i>		<i>Heart (whole)</i>		<i>Kidney</i>	
	$\mu$	$\mu_{en}$	$\mu$	$\mu_{en}$	$\mu$	$\mu_{en}$	$\mu$	$\mu_{en}$
0.015	10.99	10.33	9.44	7.94	1.50	1.19	2.50	2.16
0.02	4.77	4.37	4.33	3.63	0.74	0.48	1.16	0.89
0.03	1.55	1.28	1.49	1.17	0.36	0.14	0.48	0.26
0.04	0.76	0.54	0.75	0.52	0.26	0.06	0.31	0.11
0.05	0.47	0.28	0.47	0.27	0.22	0.04	0.25	0.06
0.06	0.35	0.17	0.35	0.17	0.20	0.03	0.22	0.044
0.08	0.24	0.081	0.24	0.083	0.18	0.026	0.19	0.031
0.10	0.20	0.052	0.20	0.054	0.17	0.025	0.17	0.028
0.15	0.15	0.034	0.16	0.036	0.15	0.027	0.15	0.028
0.20	0.13	0.031	0.14	0.032	0.14	0.029	0.13	0.029
0.30	0.11	0.031	0.12	0.032	0.12	0.032	0.12	0.031
0.40	0.01	0.031	0.10	0.032	0.11	0.033	0.10	0.032
0.50	0.09	0.031	0.09	0.032	0.10	0.033	0.09	0.032
0.60	0.08	0.031	0.09	0.032	0.09	0.033	0.09	0.032
0.80	0.07	0.030	0.08	0.031	0.08	0.032	0.08	0.031
1.0	0.07	0.029	0.07	0.030	0.07	0.031	0.07	0.030
1.5	0.05	0.027	0.06	0.027	0.06	0.028	0.06	0.027
2.0	0.05	0.025	0.05	0.025	0.05	0.026	0.05	0.025

<i>E</i> (MeV)	<i>Liver</i>		<i>Lungs</i>		<i>Muscle</i>		<i>Ovaries</i>	
	$\mu$	$\mu_{en}$	$\mu$	$\mu_{en}$	$\mu$	$\mu_{en}$	$\mu$	$\mu_{en}$
0.015	1.74	1.42	1.60	1.29	1.63	1.32	1.55	1.24
0.02	0.84	0.57	0.78	0.52	0.79	0.53	0.76	0.49
0.03	0.39	0.17	0.37	0.15	0.37	0.15	0.37	0.14
0.04	0.27	0.075	0.27	0.068	0.27	0.07	0.26	0.066
0.05	0.23	0.045	0.22	0.042	0.22	0.043	0.22	0.041
0.06	0.21	0.034	0.20	0.032	0.20	0.033	0.20	0.031
0.08	0.18	0.027	0.18	0.026	0.18	0.026	0.18	0.026
0.10	0.17	0.026	0.17	0.025	0.17	0.026	0.17	0.025
0.15	0.15	0.028	0.15	0.028	0.15	0.028	0.15	0.028
0.20	0.14	0.030	0.14	0.029	0.14	0.029	0.14	0.030
0.30	0.12	0.032	0.12	0.032	0.12	0.032	0.12	0.032
0.40	0.11	0.033	0.11	0.033	0.11	0.033	0.11	0.033
0.50	0.10	0.033	0.10	0.033	0.10	0.033	0.10	0.033
0.60	0.09	0.033	0.09	0.033	0.09	0.033	0.09	0.033
0.80	0.08	0.032	0.08	0.032	0.08	0.032	0.08	0.032
1.0	0.07	0.031	0.07	0.031	0.07	0.031	0.07	0.031
1.5	0.06	0.038	0.06	0.028	0.06	0.028	0.06	0.028
2.0	0.05	0.026	0.05	0.026	0.05	0.026	0.05	0.026



TABLE V—*Continued*

$E(\text{MeV})$	<i>Pancreas</i>		<i>Spleen</i>		<i>Tongue</i>	
	$\mu$	$\mu_{\text{en}}$	$\mu$	$\mu_{\text{en}}$	$\mu$	$\mu_{\text{en}}$
0.015	1.55	1.24	1.53	1.21	1.49	1.19
0.02	0.76	0.50	0.75	0.49	0.74	0.47
0.03	0.36	0.14	0.36	0.14	0.36	0.14
0.04	0.26	0.066	0.26	0.065	0.26	0.063
0.05	0.22	0.041	0.22	0.040	0.22	0.040
0.06	0.20	0.031	0.20	0.031	0.20	0.031
0.08	0.18	0.026	0.18	0.026	0.18	0.026
0.10	0.17	0.025	0.17	0.025	0.17	0.025
0.15	0.15	0.028	0.15	0.027	0.15	0.028
0.20	0.14	0.030	0.14	0.029	0.14	0.030
0.30	0.12	0.032	0.12	0.032	0.12	0.032
0.40	0.11	0.033	0.11	0.033	0.11	0.033
0.50	0.10	0.033	0.10	0.033	0.10	0.033
0.60	0.09	0.033	0.09	0.033	0.09	0.033
0.80	0.08	0.032	0.08	0.032	0.08	0.032
1.0	0.07	0.031	0.07	0.031	0.07	0.031
1.5	0.06	0.028	0.06	0.028	0.06	0.028
2.0	0.05	0.026	0.05	0.026	0.05	0.026

excellent agreement. The Tipton–Cook bone data are for *wet* bones (9) and the rest refer to the femur bones. Our results for bone (femur) are in a good agreement with the Spiers–Woodard data (12), but they differ significantly in the C and Ca contents from the Tipton–Cook (9) and the ICRU data (10). Epp *et al.* (13) give the chemical composition of mouse metaphyseal bone as follows: H (5.59%), C (2.37%), N (3.77%), O (54.66%), P (7.06%), S (0.44%), and Ca (16.1%).

#### PHOTON DOSIMETRY DATA

The photon mass attenuation coefficient  $\mu$  and mass energy absorption coefficient  $\mu_{\text{en}}$  for our tissue samples are given in Table V. The basic photon data were taken from the Hubbell compilation (5) except for the Cl data which were taken from the Storm–Israel compilation (14). Our  $\mu$ 's include the coherent scattering effects (4), and the  $\mu_{\text{en}}$  values are those corrected for the bremsstrahlung losses by secondary electrons.

In the energy range considered here, the molecular binding should have little effect on  $\mu$  and  $\mu_{\text{en}}$  (6, 7), and the effective values of these coefficients for the tissues are obtained merely by adding the atomic coefficients weighted by the chemical compositions. Our values of  $\mu$  and  $\mu_{\text{en}}$  for muscle and bone are in accord with those of Evans (4).

It is evident from Table V that the coefficient  $\mu$  and  $\mu_{\text{en}}$  are essentially the same for all tissues considered in this paper except for low-energy photons. At low energies, an appreciable variation in  $\mu$  and  $\mu_{\text{en}}$  exists among the tissues. It may be stated that photons of a given energy have higher LET in a higher

effective  $Z$  material than in a lower effective  $Z$  material, although the energy loss per gram by the photons may be the same in both materials.

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# EXHIBIT U

# Fibres, Films, Plastics and Rubbers

A Handbook of Common Polymers

Compiled by

**W. J. ROFF,**

B.SC., M.SC.

*formerly at the Shirley Institute, Cotton Silk and  
Man-made Fibres Research Association, Manchester*

and

**J. R. SCOTT,**

PH.D., F.R.I.C., F.INST.P., F.I.R.I.

*Rubber and Plastics Research Association, Shawbury,  
Shropshire (Director 1940–58)*

with the assistance of

**J. PACITTI,**

M.A.

*Rubber and Plastics Research Association*

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## SECTION 41

## SILICONES

*Rubbers and Resins*

*With notes on fluids, dispersions, organochlorosilanes, aminosilanes, silicon esters and 'bouncing putty'*

## SYNONYMS AND TRADE NAMES

Organo-silicon oxide polymers, Polysiloxanes. *Rubbers* Adrub, LS-53, LS-63, NSR, Polysil, Silastic, Silastomer, Silcoset, Silicol, Sil-O-Flex, SKT (and variants denoted by extra letters); DP, E, K, KW, MS, S, SE and W followed by numbers. *Resins* Dri-film, Sylgard; DC, DP, R, SR followed by numbers.

## GENERAL CHARACTERISTICS

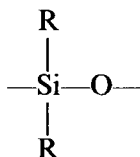
*Raw silicone rubbers* are transparent, colourless, 'limp', virtually fluid materials (viscosity  $10^7$  to  $4 \times 10^7$  cSt), not generally miscible with other rubbers. They are marketed (a) as the raw 'gums', (b) compounded mixes containing fillers, vulcanising agents, etc. (see §41.4), (c) solutions, and (d) spreading pastes, based on low molecular weight 'gums'.

*Vulcanisates* vary little in properties over a wide temperature range, and have exceptional resistance to deterioration during prolonged heating and to oxidation and ozone attack. Chemical resistance is good, and electrical properties are excellent. At normal temperatures their strength is poorer than for organic rubbers, but equal to these at elevated temperatures.

*Uncured silicone resins* are marketed as: (a) powder or flake, (b) moulding compositions (containing filler, etc.), (c) fluids 3500–9000 cP, and (d) solutions. They are not miscible with organic resins unless containing a high proportion of phenyl groups (see §41.1).

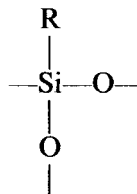
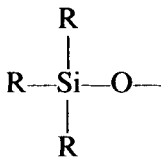
*Cured resins* are very stable to prolonged heating in air (apart from a gradual loss in weight, (see §41.32)), resistant to chemical attack (except organic liquids and strong acids), and have good electrical properties and outstanding water-repellance. Their strength is generally inferior to that of organic resins.

## 41.1 STRUCTURE

*Simplest Fundamental Unit*

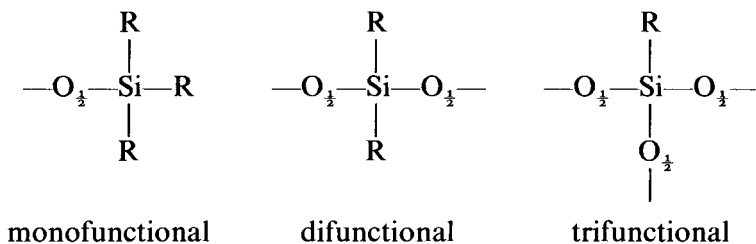
where R is an organic substituent (usually  $\text{CH}_3\text{—}$ ).

Additional to the above difunctional unit (**D**), there are mono-functional (**M**) and trifunctional (**T**) units, i.e.



## SILICONES

*Note.* The units shown above must be so linked together that there is always *one* oxygen atom between two adjacent silicon atoms; to ensure this condition, the units are sometimes written as follows, the  $O_{\frac{1}{2}}$  indicating that an oxygen atom is shared between the two silicon atoms.



In *silicone rubbers* the molecule is a substantially linear chain of **D** units with **M** end-units, and R is usually a hydrocarbon radical. The main types are: (i) general-purpose dimethyl or 'methyl' silicone rubber, where R is  $\text{CH}_3-$ ; (ii) cold-resistant methylphenyl silicone rubber, with 5–15 mol. %  $\text{CH}_3-$  replaced by  $\text{C}_6\text{H}_5-$ ; (iii) readily cross-linkable methylvinyl silicone rubber, with 0.1–4.5 mol. %  $\text{CH}_3-$  replaced by  $\text{CH}_2=\text{CH}-$ ; (iv) room-temperature vulcanising or 'RTV' rubber, containing H, OH, alkoxy or acyloxy groups; (v) swelling-resistant silicone rubber, containing cyanoalkyl or fluoro-groups, e.g.  $\text{CF}_3\text{CH}_2\text{CH}_2-$ .

In *silicone resins* there are more 'T' units, which form branching points or cross-links (by condensation from the  $-\text{OH}$  groups formed by hydrolysis of a trichlorosilane, *see* §41.21), and thus make possible a higher degree of 'curing'. The R groups are generally alkyl (usually methyl) and phenyl. Methyl groups alone give hard but relatively weak resins; longer alkyl groups make the resin softer, less heat-resistant and more soluble. Phenyl groups increase strength and heat-resistance, but give a brittle resin, hence the best result is obtained with phenyl plus methyl groups.

**Molecular weight** Raw rubbers: mean, normally  $4 \times 10^5$  to  $1.5 \times 10^6$ ; extreme values: 2500,  $2.8 \times 10^6$ . Degree of polymerisation: mean, 4000–20 000.

**X-ray data** Polydimethylsiloxane is amorphous but shows crystallinity when cooled or stretched; the monoclinic cell contains 6 monomer units:  $\beta = 60^\circ$ ,  $a = 13.0 \text{ \AA}$ ,  $b$  (identity period) =  $8.3 \text{ \AA}$ ;  $c = 7.75 \text{ \AA}$ .

## 41.2 CHEMISTRY

### 41.21 PREPARATION

*Starting materials.* These are normally organosilicon chlorides or

# EXHIBIT V

## GYNECOLOGY

# Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque

Bryan N. Brown, PhD; Deepa Mani, MBBS; Alexis L. Nolfi, BS; Rui Liang, MD;  
Steven D. Abramowitch, PhD; Pamela A. Moalli, MD, PhD

**OBJECTIVE:** We sought to determine the predominant cell type (macrophage, T lymphocyte, B lymphocyte, mast cell) within the area of implantation of the prototypical polypropylene mesh, Gynemesh PS (Ethicon, Somerville, NJ); and to determine the phenotypic profile (M1 proinflammatory, M2 antiinflammatory) of the macrophage response to 3 different polypropylene meshes: Gynemesh PS (Ethicon), and 2 lower-weight, higher-porosity meshes, UltraPro (Ethicon) and Restorelle (Coloplast, Humblebaek, Denmark).

**STUDY DESIGN:** Sacrocolpopexy was performed following hysterectomy in rhesus macaques. Sham-operated animals served as controls. At 12 weeks postsurgery, the vagina-mesh complex was excised and the host inflammatory response was evaluated. Hematoxylin and eosin was used to perform routine histomorphologic evaluation. Identification of leukocyte (CD45<sup>+</sup>) subsets was performed by immunolabeling for CD68 (macrophage), CD3 (T lymphocyte), CD20 (B lymphocyte), and CD117 (mast cell). M1 and M2 macrophage subsets were identified using immunolabeling (CD86<sup>+</sup> and CD206<sup>+</sup>, respectively), and further evaluation was performed using enzyme-linked immunosorbent assay for 2 M1 (tumor necrosis factor- $\alpha$  and interleukin [IL]-12) and 2 M2 (IL-4 and IL-10) cytokines.

**RESULTS:** Histomorphologic evaluation showed a dense cellular response surrounding each mesh fiber. CD45<sup>+</sup> leukocytes accounted

for  $21.4 \pm 5.4\%$  of total cells within the perimesh area captured in a  $\times 20$  field, with macrophages as the predominant leukocyte subset ( $10.5 \pm 3.9\%$  of total cells) followed by T lymphocytes ( $7.3 \pm 1.7\%$ ), B lymphocytes ( $3.0 \pm 1.2\%$ ), and mast cells ( $0.2 \pm 0.2\%$ ). The response was observed to be more diffuse with increasing distance from the fiber surface. Few leukocytes of any type were observed in sham-operated animals. Immunolabeling revealed polarization of the macrophage response toward the M1 phenotype in all mesh groups. However, the ratio of M2:M1 macrophages was increased in the fiber area in UltraPro ( $P = .033$ ) and Restorelle ( $P = .016$ ) compared to Gynemesh PS. In addition, a shift toward increased expression of the antiinflammatory cytokine IL-10 was observed in Restorelle as compared to Gynemesh PS ( $P = .011$ ).

**CONCLUSION:** The host response to mesh consists predominantly of activated, proinflammatory M1 macrophages at 12 weeks postsurgery. However, this response is attenuated with implantation of lighter-weight, higher-porosity mesh. While additional work is required to establish causal relationships, these results suggest a link among the host inflammatory response, mesh textile properties, and clinical outcomes in the repair of pelvic organ prolapse.

**Key words:** cytokines, inflammatory response, macrophage phenotype, polypropylene mesh, rhesus macaque

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More than 250,000 women per year in the United States will undergo surgery for the treatment of pelvic organ prolapse, with direct costs totaling >\$1 billion.<sup>1-3</sup> Native tissue repair has a recurrence rate of 40% at 2 years<sup>4,5</sup>; therefore, mechanical reinforcement of tissues using synthetic mesh has increased over the last decade.<sup>6</sup> While

From the Departments of Bioengineering (Drs Brown, Abramowitch, and Moalli and Ms Nolfi) and Obstetrics, Gynecology, and Reproductive Sciences (Drs Brown, Liang, Abramowitch, and Moalli), and McGowan Institute for Regenerative Medicine (Drs Brown, Mani, and Moalli), University of Pittsburgh; and Magee—Womens Research Institute (Drs Liang and Moalli), Pittsburgh, PA.

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Corresponding author: Pamela A. Moalli, MD, PhD. [pmoalli@mail.magee.edu](mailto:pmoalli@mail.magee.edu)

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TABLE 1

**Mechanical and structural characteristics associated with each mesh<sup>12,26</sup>**

	Gynemesh PS (Ethicon)	UltraPro (Ethicon)	Restorelle (Coloplast)
Weight, g/m <sup>2</sup>	44	31	19
Pore size, $\mu$ m	2240	$\geq 4000^a$	2370
Porosity, %	64 $\pm$ 2.1	69 $\pm$ 1.8	78 $\pm$ 3.0
Stiffness, N/mm	28 $\pm$ 2.7	22 $\pm$ 2.8	11 $\pm$ 0.89

<sup>a</sup> UltraPro contained resorbable component (poliglecaprolactone 25) in addition to polypropylene allowing it to have very large pores (4 mm) when this component is resorbed; values reported with resorbable component dissolved.

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mesh implantation has been shown to improve anatomical outcomes in the anterior and apical compartments, complications are observed, particularly with transvaginal placement,<sup>7-11</sup> including mesh exposure through the vaginal wall, shrinkage, erosion, and pain.

Recent work suggests that mesh exposures may be induced by stress shielding. That is, a mismatch in stiffness between the mesh and tissue lead to degeneration of the underlying vagina and a loss of mechanical integrity over time. This maladaptive remodeling response precipitates atrophy of the smooth muscle layer associated with a decrease in contractility as well as a shift in tissue extracellular matrix composition and a loss of biomechanical integrity.<sup>12-14</sup> Differences in mesh properties (weight, pore size, porosity, stiffness) were shown to be related to the degree to which this degenerative process occurs, with higher-weight, lower-porosity, and increased-stiffness mesh being associated

with increased vaginal tissue degradation. Mesh with higher weight, lower porosity, and increased stiffness has also been suggested to result in increased rates of complications in clinical practice.<sup>15,16</sup>

Mesh complications may also be attributable to the inflammatory processes associated with the macrophage-predominated foreign body reaction mounted by the host following implantation. Without question, the long-term presence of activated proinflammatory cells can have a negative impact on the ability of a material to function as intended. However, a number of recent studies have demonstrated that the macrophage response is also an essential component of the process leading to tissue incorporation, and functional remodeling of implanted materials, suggesting the potential for phenotypic dichotomy in the host response.<sup>17,18</sup> Indeed, macrophages have been classified as having diverse and plastic phenotypes along a continuum between M1 (classically activated; proinflammatory) and M2 (alternatively

activated; regulatory, homeostatic) extremes.<sup>19-21</sup> An increasing number of studies in the field of biomaterials have begun to apply these paradigms and concepts, showing that macrophage polarization is a predictor of integration following implantation in multiple applications.<sup>18,22-25</sup> However, the macrophage response following implantation of surgical mesh with varying characteristics has not been described. Moreover, limited studies to date have addressed the impact of mesh implantation on the vagina—an organ with an immunologically distinct environment from that of other tissues in which the host response to mesh has been examined.

The objectives of the present study were 2-fold: (1) to determine the predominant cell type (macrophage, T lymphocyte, B lymphocyte, mast cell) within the area of implantation of the prototypical polypropylene mesh, Gynemesh PS (Ethicon, Sommerville, NJ); and (2) to determine the phenotypic profile (M1 proinflammatory, M2 antiinflammatory) of the macrophage response to 3 different polypropylene meshes: Gynemesh PS, and 2 lower-weight, higher-porosity meshes, UltraPro (Ethicon) and Restorelle (Coloplast, Humblebaek, Denmark).

## MATERIALS AND METHODS

### Mesher

The test articles consisted of 3 polypropylene meshes with varying textile and mechanical characteristics as previously described.<sup>12,26</sup> Briefly, specific weight and pore size were provided by the manufacturer. Porosity was determined using a custom-designed algorithm (Matlab, Version 8.0; Mathworks, Natick, MA) and stiffness was determined by ball burst testing. Table 1 shows the relevant mechanical and structural characteristics associated with each mesh. Of note, UltraPro is manufactured with an absorbable component (poliglecaprolactone 25) in addition to polypropylene allowing it to have very large pores (4 mm) when this component is fully absorbed.

### Animals

The samples for the present study were obtained from a larger study.<sup>12,13</sup>

TABLE 2

**Demographic data collected (age, weight, gravidity, and parity)**

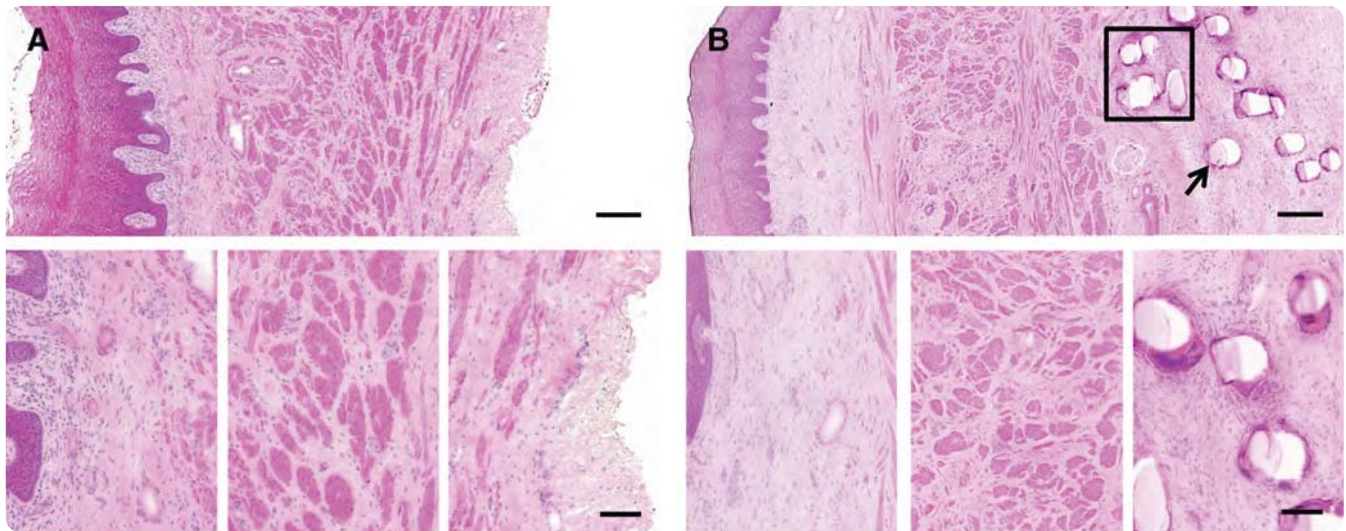
Groups	Age, y <sup>a</sup>	Parity <sup>b</sup>	Weight, kg <sup>a</sup>	POP-Q stage <sup>b</sup>
Sham	12.6 $\pm$ 2.8	3 (2, 6)	7.3 $\pm$ 1.4 <sup>c</sup>	0 (0, 1)
Gynemesh PS	12.9 $\pm$ 2.2	4 (3.8, 5)	8.2 $\pm$ 1.6	0 (0, 0)
UltraPro	13.0 $\pm$ 2.2	3.5 (2, 5.8)	7.8 $\pm$ 1.4	0 (0, 0.25)
Restorelle	13.8 $\pm$ 1.7	5 (3, 5.5)	10.0 $\pm$ 2.8 <sup>c</sup>	0.5 (0, 1.3)
P value <sup>d</sup>	.780	.970	.042	.700

<sup>a</sup> Mean  $\pm$  SD; <sup>b</sup> Median (first quartile, second quartile); <sup>c</sup> Statistical significance between groups ( $P < .05$ ); <sup>d</sup> Comparison of overall  $P$  value among groups.

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**FIGURE 1**  
**Histologic appearance of sham and mesh implanted tissues**



Representative histologic section (hematoxylin and eosin) taken from **A**, sham and **B**, Gynemesh PS groups. Top panels contain full view of histologic section at  $\times 10$  original magnification (scale bar =  $250\ \mu\text{m}$ ). Bottom panels shows higher-magnification images of **A**, subepithelial connective tissues, muscularis layer, and adventitia or **B**, mesh-tissue interface at  $\times 20$  original magnification (scale bar =  $100\ \mu\text{m}$ ). Histomorphologic appearance of response to Gynemesh PS was characteristic of response observed in all mesh-implanted groups. A dense population of mononuclear and multinucleated giant cells can be observed at mesh-tissue interface, decreasing in number with increasing distance from mesh surface. **B**, Box indicates mesh knot and arrow indicates mesh fiber.

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A subset of animals from that study was selected based on the availability of sufficient tissue samples for completion of the assays described in the present study. All animals in this study were maintained and treated according to an approved institutional animal care and use committee protocol and in accordance with the National Institutes of Health Guide for the Care and Use of Laboratory Animals. Demographic data of each animal were collected

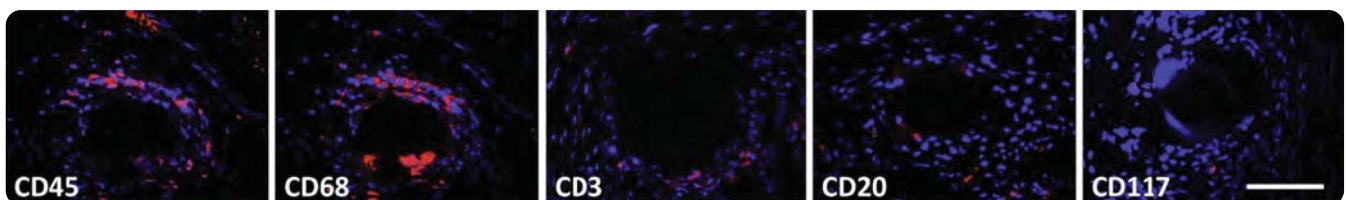
prior to surgery, including age, weight, gravidity, and parity (Table 2). In all, 32 middle-aged parous rhesus macaques underwent implantation with Gynemesh PS ( $n = 8$ ), UltraPro ( $n = 8$ ), Restorelle ( $n = 8$ ), or sham ( $n = 8$ ). Mesh was implanted by sacrocolpopexy after an abdominal hysterectomy as previously described.<sup>12,13</sup> Sacrocolpopexy was chosen as observational data suggest that complications related to this procedure are less

than those following transvaginal implantation.<sup>11,27</sup>

### Sample harvest

At 12 weeks postsurgery, vagina-mesh tissue complexes were harvested as previously described.<sup>12,13</sup> The equivalent tissues were excised in sham-operated animals. A portion of the vagina-mesh complex was embedded in optimal cutting temperature solution (Sakura Finetek USA, Torrance, CA) prior to flash freezing on liquid

**FIGURE 2**  
**Immunofluorescent labeling of cells participating in the host response to implanted mesh**



Antibodies for CD45 (panleukocyte), CD68 (macrophage), CD3 (T lymphocyte), CD20 (B lymphocyte), and CD117 (mast cell) markers were used (red). DAPI (blue) was used to label nuclei. Positively labeled cells were predominantly located at mesh surface, with fewer cells with increasing distance. All images at  $\times 40$  original magnification, scale bar =  $100\ \mu\text{m}$ .

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TABLE 3

**Total number of cells and percent surface marker positive cells in  $\times 20$  field**

Treatment (Gynemesh PS)	Total no. of cells (per $\times 20$ field)	Positive cells (per $\times 20$ field), %
CD45	514 $\pm$ 121	21.4 $\pm$ 5.4
CD68	510 $\pm$ 108	10.5 $\pm$ 3.9 <sup>a</sup>
CD3	510 $\pm$ 114	7.3 $\pm$ 1.7 <sup>b</sup>
CD20	509 $\pm$ 109	3.0 $\pm$ 1.2
CD117	508 $\pm$ 121	0.2 $\pm$ 0.2
P value	1.00 <sup>c</sup>	<.001 <sup>d</sup>

<sup>a</sup> Significance seen between CD68 and CD20, and CD68 and CD117; <sup>b</sup> Significance seen between CD3 and CD20, and CD3 and CD117; <sup>c</sup> Comparison of P value among groups, significant difference if  $P < .05$ ; <sup>d</sup> Comparison among CD68, CD3, CD20, and CD117.

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nitrogen for histologic staining and immunofluorescent labeling. Another portion was harvested and frozen for enzyme-linked immunosorbent assay (ELISA). All samples were stored at  $-80^{\circ}\text{C}$  until testing.

#### Histologic staining and immunofluorescent labeling

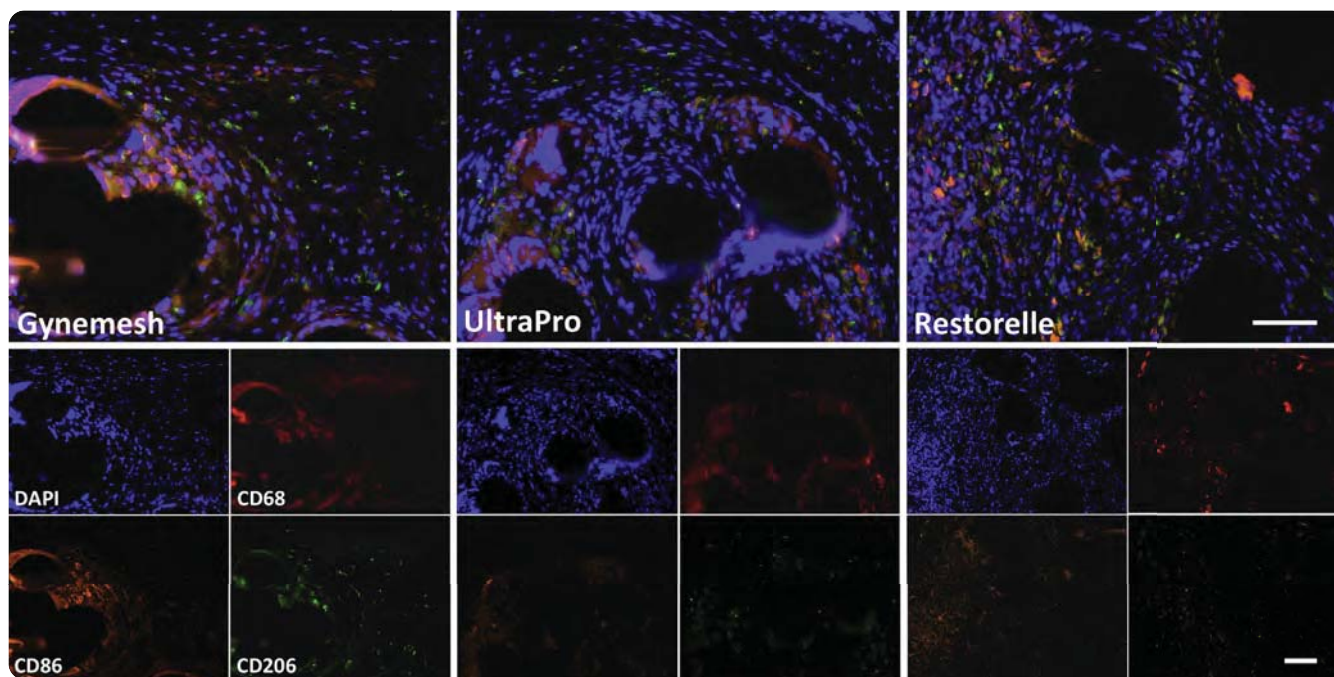
Tissue sections (7  $\mu\text{m}$ ) were cut and stored at  $-80^{\circ}\text{C}$  until use. Slides were thawed at room temperature and stained

with hematoxylin and eosin. Slides were dehydrated through a series of graded ethanol (70–100%) and xylenes prior to coverslipping. The histologic appearance of the tissue sections was then evaluated and imaged using a microscope (E600; Nikon, Melville, NY).

For immunolabeling, sections were fixed in 50:50 methanol/acetone for 10 minutes. Antigen retrieval was performed in 10 mmol/L citric acid monohydrate buffer (pH 6.0) at  $95^{\circ}\text{C}$  for 20 minutes. After cooling, the sections were incubated in copper sulfate with ammonium acetate for 20 minutes at  $37^{\circ}\text{C}$  to reduce autofluorescence. The sections were blocked with 1% normal donkey serum, 2% bovine serum albumin, 0.1% Triton-X100, and 0.1% Tween 20 at room temperature for 1 hour. Consecutive sections were then labeled with antibodies specific for leukocytes (CD45), macrophages (CD68), T lymphocytes (CD3), B lymphocytes

FIGURE 3

**Immunofluorescent labeling of M1/M2 macrophage response**



Immunofluorescent labeling with antibodies to CD68 (panmacrophage [red]), CD86 (M1 macrophage [orange]), CD206 (M2 macrophage [green]), and DAPI (nuclei [blue]). Few positive cells were observed in sham-operated animals (not shown). Predominance of M1 macrophage response was observed in Gynemesh PS, UltraPro, and Restorelle groups. Combined fluorescent (top) and individual (bottom) channels. All images at  $\times 20$  original magnification (scale bars = 100  $\mu\text{m}$ ).

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(CD20), and mast cells (CD117). Primary antibodies, diluted in blocking solution, were applied overnight at 4°C, followed by the corresponding secondary antibodies (product information and dilutions for each primary and secondary antibody are listed in [Supplemental Table](#)) and then coverslipped using aqueous mounting media containing 4',6-diamidino-2-phenylindole; (DAPI; Vectashield with DAPI; Vector Laboratories, Burlingame, CA). Localization of staining to the appropriate regions of lung, liver, kidney, spleen, lymph node, and intestine were used to verify appropriate labeling and incubation of slides without primary antibodies was used as a control. Three representative areas of the mesh-tissue interface were imaged for each individual marker using a  $\times 20$  objective on an imaging microscope (Eclipse 90i; Nikon). Quantification of cell types was performed using software (ImageJ; National Institutes of Health, Bethesda, MD). Cell counts were averaged for each sample and expressed as a percentage of total cells within a  $\times 20$  field.

Additional sections were triple-labeled with antibodies specific for a panmacrophage marker (CD68), an M1 marker (CD86), and an M2 marker (CD206) as above. Slides were imaged using a  $\times 20$  objective at the interface with either single fibers (3 images) or mesh knots (3 images) using a standardized protocol.<sup>28</sup> CD68<sup>+</sup>CD86<sup>+</sup> cells were considered to have an M1 phenotype and CD68<sup>+</sup>CD206<sup>+</sup> cells, an M2 phenotype. Cell counts were averaged for each sample and expressed as a percentage of total cells within a  $\times 20$  field. Additionally, the ratio of M2:M1 cells was calculated. Because of the scarcity of macrophages in the sham group, the ratio of M2:M1 was not reported. The perimeter of the mesh-tissue interface present in each image was calculated by tracing using ImageJ.

### ELISA assay

Frozen tissues were mechanically pulverized and homogenized in a high salt buffer (50 mmol/L Tris base, 150 mmol/L sodium chloride, and 10  $\mu$ g/mL Halt protease inhibitor cocktail, Pierce

TABLE 4

**Total number of cells, percent of positive cells, and ratio of M2/M1 macrophages seen in  $\times 20$  field (fiber)**

Treatment	Total no. of cells	M1 positive cells, %	M2 positive cells, %	Ratio, M2/M1
Sham	696 $\pm$ 370	0.8 $\pm$ 0.7 <sup>a</sup>	0.1 $\pm$ 0.0 <sup>a</sup>	—
Gynemesh PS	642 $\pm$ 215	6.8 $\pm$ 2.8	3.5 $\pm$ 2.2	0.52 $\pm$ 0.14 <sup>b</sup>
UltraPro	768 $\pm$ 232	7.3 $\pm$ 2.6	4.6 $\pm$ 1.5	0.66 $\pm$ 0.08
Restorelle	610 $\pm$ 291	7.0 $\pm$ 3.7	4.6 $\pm$ 2.1	0.67 $\pm$ 0.09
P value <sup>c</sup>	.700	<.001	<.001	<.001

<sup>a</sup> Significance seen between sham and Gynemesh PS, sham and UltraPro, and sham and Restorelle; <sup>b</sup> Significance seen between Gynemesh PS and UltraPro, and Gynemesh PS and Restorelle; <sup>c</sup> Comparison of P value among groups, significant difference if  $P < .05$ .

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Biotechnology, Rockford, IL). After centrifugation, supernatants were collected. Using the DC protein assay (Bio-Rad, Hercules, CA), protein concentrations of all extracts were determined so that all sample volumes contained 40  $\mu$ g of protein. Amounts of proinflammatory M1 (tumor necrosis factor- $\alpha$ , and interleukin [IL]-12p70) and antiinflammatory M2 (IL-10, IL-4) cytokines were assessed using commercially available ELISA assays (Life Technologies, Carlsbad, CA). Both the concentrations of individual cytokines and the ratio of M2/M1 cytokines ([IL-10 + IL-4]/[tumor necrosis factor- $\alpha$  + IL-12]) were calculated.

### Statistical analysis

Statistical comparisons were made using software (SPSS 18.0; SPSS Inc, Chicago, IL). Primate demographic and

immunolabeling data were assessed using 1-way analysis of variance with a Tukey post hoc procedure. As cytokine data were nonparametric, a Kruskal–Wallis test with a Bonferroni-adjusted alpha after pairwise comparisons was performed for each group. A Spearman correlation was used to examine the relationship between the number of M1 and M2 cells and mesh perimeter in each image. A  $P$  value  $< .05$  was used to determine significance.

### RESULTS

Animals had similar age, parity, and pelvic organ prolapse quantification (POP-Q) stage ([Table 2](#)). The POP-Q staging methods utilized were the same as that utilized in human beings adjusted to account for the shorter length of the macaque vagina.<sup>29</sup> Animals in the Restorelle group weighed more than the

TABLE 5

**Total number of cells, percent of positive cells, and ratio of M2/M1 macrophages seen in  $\times 20$  field (knot)**

Treatment	Total no. of cells	M1 positive cells, %	M2 positive cells, %	Ratio, M2/M1
Sham	679 $\pm$ 327	0.1 $\pm$ 0.1 <sup>a</sup>	0.1 $\pm$ 0.0 <sup>a</sup>	—
Gynemesh PS	630 $\pm$ 230	8.3 $\pm$ 4.7	4.4 $\pm$ 2.3	0.57 $\pm$ 0.11
UltraPro	722 $\pm$ 214	9.2 $\pm$ 2.8	5.3 $\pm$ 1.0	0.61 $\pm$ 0.18
Restorelle	575 $\pm$ 104	8.4 $\pm$ 2.6	4.9 $\pm$ 1.8	0.60 $\pm$ 0.11
P value <sup>b</sup>	.620	<.001	<.001	<.001

<sup>a</sup> Significance seen between sham and Gynemesh PS, sham and UltraPro, and sham and Restorelle; <sup>b</sup> Comparison of P value among groups, significant difference if  $P < .05$ .

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TABLE 6

**Correlation between percentage of positive cells and mesh area in  $\times 20$  image**

	M1 cells vs area, %		M2 cells vs area, %	
	Correlation coefficient	P value	Correlation coefficient	P value
Gynemesh PS	0.39	.006	0.44	.002
UltraPro	0.35	.015	0.23	.113
Restorelle	0.24	.098	0.22	.136
All mesh	0.30	.001	0.23	.006

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other groups ( $P = .042$ ); however, weight did not correlate with any of the measured outcomes ( $P > .36$  for all). One animal in the study demonstrated a mesh exposure into the vagina. There were no erosions into adjacent structures.

### Histologic analysis

All samples had an intact and qualitatively normal vaginal epithelium as well as a clearly delineated subepithelium, muscular layer, and adventitia (Figure 1). The subepithelial tissues were histologically similar across all groups, with few differences observed between sham and mesh-implanted animals. The largest differences between samples occurred in the smooth muscle layer as previously described, in which the Gynemesh PS induced the most negative impact.<sup>13</sup> All mesh-implanted animals elicited an inflammatory reaction to individual mesh fibers and around knots consisting of a dense infiltrate of mononuclear cells and

formation of a fibrous capsule. The response was highly localized with fewer cells observed with increasing distance from the mesh. Multinucleated giant cells were observed at the surface of some, but not all, fibers and knots, regardless of mesh type. The cells at the mesh-tissue interface were predominantly mononuclear in appearance and few, if any, polymorphonuclear cells (neutrophils) were observed. The adventitial layer in sham-operated animals was qualitatively normal, consisting of well-organized loose connective tissue.

### Characterization of the immune response to polypropylene mesh

CD45<sup>+</sup> cells (panleukocyte) were observed predominantly at the mesh-tissue interface and in the perimesh space in the adventitia with few, if any of these cells within the subepithelium or muscularis of Gynemesh PS-implanted animals indicating a highly localized inflammatory response. CD68<sup>+</sup> cells

(macrophage) were the immune cell type found in the greatest density immediately surrounding each mesh fiber, while other cells types were fewer in number and found to be located more distantly from the mesh surface (Figure 2). CD45<sup>+</sup> cells accounted for  $21.4 \pm 5.4\%$  of total cells within  $\times 20$  fields at the mesh-tissue interface. CD68<sup>+</sup> cells (macrophages,  $10.5 \pm 3.9\%$ ) were found to be the predominant leukocyte subtype, followed by CD3<sup>+</sup> (T lymphocyte,  $7.3 \pm 1.7\%$ ), CD20<sup>+</sup> (B lymphocyte,  $3.0 \pm 1.2\%$ ), and CD117<sup>+</sup> (mast,  $0.2 \pm 0.2\%$ ) cells. Although the percentage of macrophages was 44% greater than that of T cells, no significant statistical differences were observed between these two. Both the percentage of macrophages and T lymphocytes were significantly higher than the percentage of B lymphocytes or mast cells (all  $P < .001$ ) (Table 3). No differences in the total number of DAPI<sup>+</sup> cells were observed between image sets for each antibody. Few positively labeled cells of any type were observed within the sham ( $< 5$  per  $\times 20$  field) and, therefore, quantitative analysis of immunolabeled slides was not performed for this group.

### Analysis of macrophage phenotype

In all implanted animals, the macrophage response to mesh was observed to be predominantly of the M1 phenotype with fewer cells of either phenotype observed with increasing distance from the mesh surface (Figure 3). In areas with individual fibers, the percentage of M1 cells per  $\times 20$  field was increased in mesh-implanted groups (Gynemesh PS

TABLE 7

**Individual and ratio values of antiinflammatory and proinflammatory cytokines**

Groups	IL-10 <sup>a</sup>	IL-4 <sup>a</sup>	TNF- $\alpha$ <sup>a</sup>	IL-12p70 <sup>a</sup>	(IL-10 + IL-4)/(TNF- $\alpha$ + IL-12p70) <sup>b</sup>
Sham	$1.30 \pm 0.31$	$0.33 \pm 0.01$	$0.38 \pm 0.11$	$0.26 \pm 0.06$	$2.58 \pm 0.52$
Gynemesh PS	$1.03 \pm 0.20$	$0.29 \pm 0.08$	$0.33 \pm 0.12$	$0.27 \pm 0.05$	$2.17 \pm 0.78^c$
UltraPro	$1.12 \pm 0.22$	$0.27 \pm 0.11$	$0.28 \pm 0.15$	$0.23 \pm 0.07$	$3.01 \pm 0.90$
Restorelle	$1.27 \pm 0.22$	$0.263 \pm 0.05$	$0.26 \pm 0.05$	$0.30 \pm 0.15$	$3.36 \pm 0.60^c$
P value <sup>d</sup>	.014	.358	.084	.386	.004

IL, interleukin; TNF, tumor necrosis factor.

<sup>a</sup> pg/ $\mu$ g Total protein, mean  $\pm$  SD; <sup>b</sup> Unitless, mean  $\pm$  SD; <sup>c</sup> Statistical significance between groups ( $P < .05$ ); <sup>d</sup> Comparison of overall P value among groups.

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$6.7 \pm 2.8\%$ ,  $P = .003$ ; UltraPro  $7.3 \pm 2.6\%$ ,  $P = .002$ ; Restorelle  $7.0 \pm 3.7\%$ ,  $P = .008$ ) relative to sham ( $0.8 \pm 0.7\%$ ). The percentage of M2 cells was also increased in mesh-implanted groups (Gynemesh PS  $3.5 \pm 2.2\%$ ,  $P = .046$ ; UltraPro  $4.6 \pm 1.5\%$ ,  $P = .001$ ; Restorelle  $4.6 \pm 2.1\%$ ,  $P = .001$ ) relative to sham ( $0.07 \pm 0.03\%$ ). The percentage of M2 cells around individual fibers was similar in lighter-weight, higher-porosity meshes (UltraPro,  $P = .24$ ; Restorelle,  $P = .32$ ) as compared to Gynemesh PS. However, the M2/M1 ratio around individual fibers was higher for UltraPro ( $P = .033$ ) and Restorelle ( $P = .016$ ) as compared to Gynemesh PS (Table 4). However, the M2/M1 ratio around individual fibers was higher for UltraPro ( $P = .033$ ) and Restorelle ( $P = .016$ ) as compared to Gynemesh PS (Table 4).

M1 macrophages around mesh knots were increased in the presence of mesh (Gynemesh PS  $8.3 \pm 4.7\%$ , UltraPro  $9.2 \pm 2.8\%$ , Restorelle  $8.4 \pm 2.6\%$ ) relative to sham ( $0.09 \pm 0.09\%$ ) ( $P < .001$ ). M2 macrophages also increased with mesh implantation (Gynemesh PS  $4.4 \pm 2.3\%$ , UltraPro  $5.3 \pm 1.0\%$ , Restorelle  $4.94 \pm 1.8\%$ ) as compared to sham ( $0.09 \pm 0.07\%$ ) ( $P < .001$ ). However, in contrast to single fibers, no significant differences in the percentage of M1 and M2 cells or the M2/M1 ratio was observed in areas of mesh knots (Table 5).

The total number of cells within a  $\times 20$  field was similar in images containing fibers and knots, despite the increased area occupied by knots as compared to fibers. This suggests a more dense inflammatory response around knots as compared to fibers. Though elevated in images with knots, no statistically significant differences in the percentage of M1 and M2 cells was found between images containing fibers and knots for any mesh ( $P = .41$ ,  $.18$ , and  $.51$  for Gynemesh PS, UltraPro, and Restorelle, respectively). A Spearman rho test was used to determine whether there was a correlation between mesh perimeter and percentage of M1 and M2 cells in a given image. Results varied by mesh (Table 6), however, examination of correlations across all mesh types demonstrated a

significant correlation between mesh perimeter and the percentage of M1 ( $r = .30$ ,  $P < .001$ ) and M2 ( $r = 0.23$ ,  $P = .006$ ) cells within a given image.

No statistically significant differences were observed between groups for individual cytokines (all  $P > .05$ ) except IL-10 (overall  $P = .011$ ), which was 23% higher in Restorelle as compared to Gynemesh PS ( $P = .011$ ). The ratio of M2/M1 cytokines was also increased in Restorelle-implanted vagina as compared to Gynemesh PS ( $P = .003$ ) (Table 7).

### COMMENT

The present study sought to define the host inflammatory response to 3 polypropylene meshes with distinct textile properties following implantation via sacrocolpopexy in the rhesus macaque. The most significant findings were that, while all mesh materials elicited a predominantly M1 macrophage profile, lower-weight, higher-porosity meshes (UltraPro and Restorelle) elicited a shift in the M2/M1 macrophage ratio in the area around individual mesh fibers. The concentration of antiinflammatory cytokine IL-10 was higher in the Restorelle group as compared to Gynemesh PS, with levels approaching that of the sham-operated group, reflecting differences in the overall local microenvironment associated with the implantation of different mesh types.

This shift in the M2/M1 ratio in the area of individual fibers following the implantation of lighter-weight, higher-porosity meshes, but not following the implantation of a heavier-weight, lower-porosity mesh, is in line with previous observations of abdominal hernia meshes suggesting that “mesh burden,” defined as the amount of mesh in contact with tissue, may be a critical factor in the immune response to polypropylene mesh.<sup>30-33</sup> These studies show that polypropylene meshes invariably elicit a foreign body reaction, with the amount of chronic inflammation and scarring proportional to pore size, with an increase in the inflammatory response and scarring over time in meshes with decreased pore size.<sup>32</sup> This phenomenon of increased inflammatory scarring with decreased

pore size, termed “bridging fibrosis,” suggests that increased fiber density (ie, mesh burden) corresponds to increased inflammatory and fibrotic reactions due to overlap of the host response to multiple individual fibers in close proximity. In the present study, mesh perimeter was found to be positively correlated with the percentage of both M1 and M2 cells present within a given image, suggesting a link between mesh burden and the host inflammatory response exists for meshes implanted in the vagina.

The results of the present study also suggest that macrophage phenotype may influence tissue integration and/or degradation following mesh implantation. Indeed, corresponding to previous findings that the lighter, wider-pore, higher-porosity meshes induced fewer negative effects on the vagina than did Gynemesh PS,<sup>12-14</sup> the present study observed a higher ratio of M2 to M1 phenotype (macrophage polarization) and increased antiinflammatory cytokine IL-10 in the lighter but not in the heavier mesh-implanted vagina. Similar findings of improved material integration and remodeling associated with increased M2 macrophage populations have been observed in a number of other studies such as those in cardiac, dermal, and orthopedic applications of implantable materials of both biologic and synthetic origin.<sup>18,22-25</sup> In a recent study,<sup>18</sup> 15 biologically derived surgical meshes were examined for both histologic outcomes and macrophage polarization profile at 14 and 35 days postimplantation in a partial-thickness rodent abdominal wall defect model. The study showed that the number of M2 cells and the M2:M1 ratio at 14 days postimplantation were strongly correlated with semiquantitative scoring of the histomorphologic appearance of the site of implantation at 14 days and were also predictive of the downstream histologic outcome at 35 days postimplantation. Taken together, this suggests that materials that elicit a higher percentage of M2 cells at the tissue interface may be associated with improved tissue integration and fewer complications in the long term.

There were a number of limitations of the present study. First, only 1 time point was examined, representing a cross-sectional snapshot of a highly dynamic inflammatory process. It should also be noted that, due to the presence of an absorbable component (poliglecaprolactone 25), the mesh burden associated with the UltraPro mesh and the local composition of the material is also dynamic. Thus, the host response to UltraPro may have a transient component not present in the other mesh materials. While statistically significant differences were observed between materials at 90 days, the magnitude of these differences was relatively small. Evaluation of macrophage phenotype at earlier times may have yielded larger differences, but is likely not possible in a primate model due to cost and ethical considerations. Second, only 1 marker of M1 and M2 macrophage phenotypes was used in the present study. It is well known that macrophage phenotype occurs along a spectrum between M1 and M2 with multiple intermediate phenotypes.<sup>21</sup> While this represents the first such attempt to measure macrophage polarization in response to material implantation within the vagina, future studies are needed to better define both the phenotype and the function of the cells participating in the host response to implanted mesh to better understand their impact on tissue integration vs degradation and the occurrence of complications in the long term.<sup>34,35</sup> Third, the present study describes a macrophage-centered approach to the evaluation of the host response at the mesh-tissue interface. Future analyses could specifically evaluate the inflammatory reaction as a function of distance from the mesh surface or within pore spaces. This may be particularly important given that additional cell types, including a notable presence of T lymphocytes, was observed with increasing distance from the mesh surface. Lastly, only mesh introduced by sacrocolpopexy was examined in the present study. Future studies should examine whether there are differences in the host response between mesh introduced by sacrocolpopexy vs transvaginally, and attempt to correlate the findings to the differences in rates of complications observed for these 2 procedures.

In conclusion, the host response to polypropylene mesh consists predominantly of macrophages polarized to a proinflammatory M1 phenotype at 12 weeks postsurgery. However, implantation of lighter-weight, higher-porosity mesh generally attenuated the proinflammatory M1 response. These findings correlate with those of a previous study demonstrating that lighter-weight, higher-porosity mesh was also associated with fewer negative effects on vaginal tissue quality. This suggests that the chronic M1 proinflammatory response to mesh may drive tissue degradation eventually leading to mesh exposures over time similar to what is observed clinically; however, additional work is required to establish a causal relationship. An improved scientific understanding of the mechanisms of the host response to synthetic mesh materials placed in the vagina has the potential to significantly affect the design of next-generation mesh materials, inform clinical practices, and improve outcomes in pelvic floor repair. ■

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## APPENDIX

## SUPPLEMENTAL TABLE

## Antibodies used in immunofluorescence labeling

## Primary antibody

Name	Dilution	Catalog no.	Clonality	Company
Rabbit anti-CD45	1:600	ab10558	Polyclonal	Abcam
Mouse anti-CD68	1:100	ab955	Monoclonal	Abcam
Rabbit anti-CD3	1:50	A0452	Polyclonal	DAKO
Rabbit anti-CD20	1:50	ab27093	Polyclonal	Abcam
Rabbit anti-CD117	1:50	ab32363	Monoclonal	Abcam
Rabbit anti-CD86	1:150	ab53004	Monoclonal	Abcam
Goat anti-CD206	1:150	sc-34577	Polyclonal	Santa Cruz

## Secondary antibody

Name	Dilution	Catalog no.	Wavelength (nm)	Company
Alexa 594 donkey antimouse	1:100	A21203	590/617	Invitrogen
Alexa 568 donkey antirabbit	1:50 (CD3, CD20, and CD117) 1:200 (CD45)	A10042	578/603	Invitrogen
Alexa 488 donkey antigoat	1:250 (CD206)	A11055	488/519	Invitrogen
Alexa 647 donkey antirabbit	1:250 (CD86)	A31573	650/668	Invitrogen

Brown. Inflammatory response to prolapse mesh. *Am J Obstet Gynecol* 2015.

# EXHIBIT W

# Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants

Arnaud Clavé · Hannah Yahi · Jean-Claude Hammou ·  
 Suzelei Montanari · Pierre Gounon · Henri Clavé

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## Abstract

**Introduction and hypothesis** Currently, most implants used for reinforcement in surgical treatment of pelvic floor disorders are knitted monofilament polypropylene (PP). While previously recognized as inert, PP is associated with high complication rates. Some recent literature suggests polyester prosthetics based on poly(ethylene terephthalate) (PET), which may be more inert in vivo.

**Methods** A sample of 100 implants explanted from patients due to complications was examined to evaluate the relative degradation characteristics of PP and PET prosthetics.

Histological, microscopic (scanning electron microscopy, SEM) and chemical analysis (Fourier transform infrared (FTIR) spectroscopy and differential scanning calorimetry (DSC)) were conducted on these explants.

**Results** Poly(ethylene terephthalate) explants appeared to sustain less degradation in vivo than the PP explants observed in this cohort.

**Conclusions** This is the first study to evaluate synthetic implants used in a vaginal approach for pelvic floor reinforcement. The study provides evidence contrary to published literature characterizing PP as inert in such applications. Additionally, the study suggests the need for clinical trials comparatively investigating the performance of new types of monofilament prosthetics, such as those comprising PET.

**Keywords** Biomaterials · Histological examination · Pelvic floor disorders · Polyester · Polypropylene · Vaginal surgery

A. Clavé

Service de Chirurgie (Pr Lefèvre),  
 CHRU Brest Faculté de Médecine,  
 Université de Bretagne Occidentale,  
 Brest, France

H. Yahi

Service de Gynécologie (Pr Cosson), CHRU Lille,  
 Lille, France

J.-C. Hammou

Laboratoire d'Anatomopathologie,  
 Nice, France

S. Montanari

Research and Development Department, Covidien,  
 Trévoux, France

P. Gounon

Centre Commun de Microscopie Appliquée (CCMA),  
 Université de Nice Sophia-Antipolis,  
 Nice, France

H. Clavé (✉)

Département de Chirurgie Gynécologique, Clinique Saint George,  
 24, Avenue de Flirey,  
 06000 Nice, France  
 e-mail: clave.henri@wanadoo.fr

## Abbreviations

PFD	Pelvic floor disorder
PP	Polypropylene
PET	Poly(ethylene terephthalate)
PPMF	Polypropylene monofilament
LDPPMF	Low density polypropylene monofilament
HDPPMF	High density polypropylene monofilament
NKNW	Nonknitted nonwoven polypropylene
PGA	Poly(glycolic acid)
FTIR	Fourier transform infrared spectroscopy
DSC	Differential scanning calorimetry
SEM	Scanning electron microscopy

## Introduction

Pelvic floor disorder (PFD) treated surgically using autologous tissues have exhibited both high rates of failure and

recurrence [1–3]. As such, the use of synthetic meshes for this application has gained increasing popularity since the 1980s [2, 4].

The majority of implants for reinforcement of PFD are knitted from polypropylene (PP) [5]. Polypropylene implants have been collectively recognized for good tolerance. Despite some promising results reported in the literature [3, 6–8], complications remain high for an elective surgery [7, 9–11].

Mesh implants are described and classified by material (PP and poly(ethylene terephthalate) (PET) being the most popular), yarn type (monofilament or multifilament), and textile process (knitting or nonwoven techniques). Surface density expressed in weight per square centimeter and/or pore size are critical parameters for predicting the quality of tissue integration. Usually, mesh material with surface density below 50–60 g/cm<sup>2</sup>, and/or pores larger than 1.2 mm are considered low weight and/or high porosity [12, 13].

Both PP and PET are thermoplastic resins. The different yarns obtained from these materials can be prepared using different techniques leading to the following classification:

- When the yarn used to knit the mesh comprises a single thread, the mesh is considered monofilament. Single thread PP defines the prosthetic group polypropylene monofilament (PPMF). The amount and diameter of fiber used during the knitting process allows differentiation of implants between high density monofilament (HDPPMF) and implants of low density monofilament (LDPPMF).
- When the yarn used to knit the mesh consists of a multitude of fibers, the implant is called multifilament. This can be the case for both PET and PP-based materials.
- When the mesh is prepared by thermowelding of a multitude of yarns, it is called nonknitted nonwoven (NKNW) material.
- When an absorbable material is incorporated into the mesh, it results in a composite mesh. The aim of adding these materials is to improve the *in vivo* tolerance by decreasing the quantity of nonabsorbable material. This class of implants consists of yarns created from composites of PP and poly(glycolic acid) (PP/PGA).

The purpose of this study was to compare the state of alteration of different meshes commonly used in stress urinary incontinence (SUI) or pelvic organ prolapse (POP) surgery, explanted after clinical complication and to investigate potential causes of alteration.

## Materials and methods

### Sample collection

This prospective comparative study included 100 prosthetic explants surgically removed for one (or several) common

complications including exposure, infection, and/or shrinkage. The explantation procedures occurred between 2006 and 2007 by vaginal route in 13 collaborating French surgical centers that regularly use synthetic implant reinforcement in PFD surgery. The dimensions of the harvested samples were at least of 1.0 cm×0.5 cm. Each explant was rinsed and placed in a 4% neutral buffer formalin solution and then, sealed.

The samples were sent to the research team within 24 h of fixation. The brand and relevant clinical information for each explant was documented in an accompanying information file. This information file included the age of the patient, clinical indication for prosthetic placement, dates of implantation and explantation, trademark of the explanted prosthesis, reason for removal (exposure, infection, and shrinkage), and results of the bacteriological analysis (if available).

The Ethics Committee of St. George group clinic approved the study design. To protect patient identity, each sample was given a sequential specimen number unrelated to identifiable patient data.

### Histological analysis

Samples were embedded in paraffin wax, sectioned, and then, stained with hematoxylin-eosine-safran for histological analysis.

### Scanning electron microscope analysis

Morphological analysis of explants and pristine control mesh samples of the same trademark was conducted using scanning electron microscopy (SEM, JEOL 6700F). SEM images were collected at low voltage (1–5 kV).

Prior to imaging, explants and pristine samples were fixed and preserved in a 1% glutaraldehyde solution in cacodylate buffer (0.1 M, pH 7.5). Samples were rinsed in a cacodylate buffer, then, postfixed by a 1% osmium tetroxide solution, which is added to the cacodylate buffer. Fixation times were adapted to the size of the sample. Samples were further rinsed with distilled water, then, dehydrated with a series of ethanol solutions of increasing concentration. Samples were then dried using hexamethyldisilazane (Carl Roth, Karlsruhe, Germany). Each sample was sputter-coated with a 3-nm gold–palladium coating prior to analysis with the SEM.

### Chemical analysis

Chemical analysis of 32 mesh explants was carried out to characterize the degradation of mesh materials. Samples were divided into four groups (described below). Because of the small sample size and physical condition of the

explanted materials, extensive and complete chemical analysis was difficult.

- Group1: degraded PP explants (as confirmed by SEM); seven LDPPMF, nine HDPPMF, one composite, and one NKNW;
- Group2: nondegraded PP explants consisting of six LDPPMF and four HDPPMF;
- Group3: four PET explants;
- Group4: a control group of pristine implants, which consisted of one pristine LDPPMF implant (Prolene Soft®/Ethicon), one pristine HDPPMF implant (Prolene®/Ethicon), and one pristine PET implant (Parietex®/Covidien).

#### Fourier transform infrared spectroscopy

Fourier transform infrared (FTIR) spectroscopy is a spectroscopic technique widely used to facilitate determination of chemical functional groups by their absorption frequency. Different functional groups have characteristic infrared (IR) radiation absorption frequencies, generally, presented as absorbance as a function of wave number.

A Spectrum 100 (Perkin Elmer) FTIR spectrometer in attenuated total reflectance mode was used to analyze the samples. The spectra were recorded using 12 scans and 4 cm<sup>-1</sup> resolution as acquisition conditions.

Baseline IR spectra were recorded for all samples. To eliminate organic residue on explants from groups 1–3, samples were treated for 26 h with NaOCl solution (Chemie plus 12% active chlorine) at room temperature and washed with deionized water. Samples were then extracted with pure cyclohexane (Merck, Darmstadt, Germany) for 24 h at room temperature.

The control group samples (pristine samples of Prolene® and Prolene Soft®) were treated with the same protocol to determine if the cleaning process had chemically modified the material. Spectra from test groups were compared to their specific control spectra.

#### Differential scanning calorimetry

Differential scanning calorimetry (DSC) aims to identify changes in polymer morphology through observation of changes in glass transition temperature, melting temperature, and heat of fusion.

Thermal characterization of the samples was performed using a jade differential scanning calorimeter (Perkin Elmer). Samples were hermetically sealed in aluminum pans, with an empty pan used as a reference. The samples were heated from 5 to 200°C at 10°C/min. The DSC thermograms of degraded and nondegraded LDPPMF and HDPPMF were compared to their respective pristine control thermograms.

#### Statistical analyses

All statistical analyses were carried out using Minitab® 15 software. Chi-square or Fisher exact tests were used when relevant in order to compare:

- the histological results according the various families of implants; and
- the degradation rate according to the histological reaction type (infection as type 1/chronic inflammation as type 2/sclerosis as type 3).

The statistical significance level was fixed at  $p < 0.05$ .

## Results

#### Sample collection and clinical data

Of 100 explanted samples, the information files were not complete for ten of them while the other six were either too small (<2 mm<sup>2</sup>) or dried during transportation. The average period before prosthetic removal was 790.6 days (ranging from 16 to 3,295 days).

The causes for removal were distributed as follows: isolated exposures ( $n=39$ , 46%), isolated infections ( $n=14$ , 17%), shrinkage or pain ( $n=12$ , 14%), associated exposure ( $n=19$ , 22%; exposure+infection ( $n=10$  or 11.6%), exposure+shrinkage ( $n=9$  or 9.3%)). The sampling of the series is shown in Table 1.

#### Histological analysis

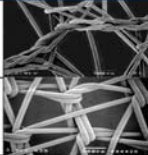

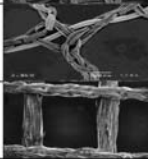
The histological study revealed three types of periprosthetic tissue reaction.

Type 1 reaction has a characteristic of an infection ( $n=37/84$ , 44%). The tissue reaction appeared identical to that observed in a periprosthetic abscess. A majority of altered polymorphonuclear neutrophils were found. This suggested an infectious process. There were no signs of periprosthetic colonization.

Type 2 reaction is presented as chronic inflammation ( $n=35/84$ , 42%) rich in giant cells and mononuclear cells. There could be a minor contamination process confirmed by the presence of some nonaltered polynuclear cells. A partial colonization of the implant was observed.

Type 3 reaction was sclerosis ( $n=12/84$ , 14%), whereby the implant was set in a pronounced fibrosis. This fibrosis was transformed to hardening with almost complete disappearance of the fibroblasts and maturation of the collagen. Implants were fully colonized, but a low infiltration rate of mononuclear cells without polynuclear cells was observed.

**Table 1** Details of the 84 explants' sampling

Designation		N	Type	SEM Pictures	Weight (g/m <sup>2</sup> )	Ø pores (mm)
PPMF N=51	LDPPMF	28	Low Density PolyPropylene Monofilament		≤50–60	≥ 1,2
	HDPPMF	23	High Density PolyPropylene Monofilament		≥60	≤ 1
Other PP N=12	NKNW	8	Non Knitted Non Woven PolyPropylene		≥60	≤ 0,5
	PPmultifilament	4	PolyPropylene Multifilament			
Composite: PP/PGA		8	Polypropylene associated to polyglactine			
PET		13	Polyethylene terephthalate			

All groups of implants showed evidence of type 1 and 2 reactions. A type 3 reaction was observed only in LDPPMF, HDPPMF, and in PET.

The results suggested a significant difference in infection and sclerosis between the type of PP explants. Multifilament PP, NKNW, and composite implants were more frequently associated with infection than PP monofilament implants (LDPPMF and HDPPMF), 70% versus 39%, respectively ( $p=0.02$ ). On the other hand, PP monofilament implants were more frequently associated with sclerosis than other PP and composite implants, 20% versus 0%, respectively ( $p=0.05$ ).

#### SEM analysis

As expected, SEM analysis of pristine meshes showed no prosthetic damage or alterations of their filaments. An explant was considered degraded if it showed morphological differences in comparison to the corresponding pristine implants. Analysis of different mesh explants showed evidence of damage to the prostheses (Fig. 1). Mesh damage included superficial degradation, which appeared as a peeling of the fiber surface, transverse cracks in the implant threads, significant cracks with disintegrated surfaces and partially detached material, and superficial or deep flaking. Fractures were variable in number and depth. Specific deteriorations correlating to implant material were not observed.

SEM revealed that 42% of the implants were degraded ( $n=35/84$ ), and 58% were intact ( $n=49/84$ ; Fig. 2). Degradation was observed only in samples implanted for at least 3 months. Other than the 3-month implantation time, no

correlation between the duration of the implant and prosthetic damage was observed (Fig. 3).

Analysis of the damage observed on the prosthetic explants showed that all types of PP implants exhibited degradation but in an uneven way according to their nature and their manufacturing process. None of the PET implants were found to be altered and degraded (Fig. 2).

A significant difference in percentage of degraded samples between histological reaction in type 1 (infection) and histological reaction in type 3 (sclerosis) was found. Evidences of PP degradation were more frequently observed when the surrounding tissue reaction was classified as infection (59% of degraded PP samples with type 1 reaction versus 20% for type 3 reaction,  $p=0.031$ ).

#### Chemical analysis

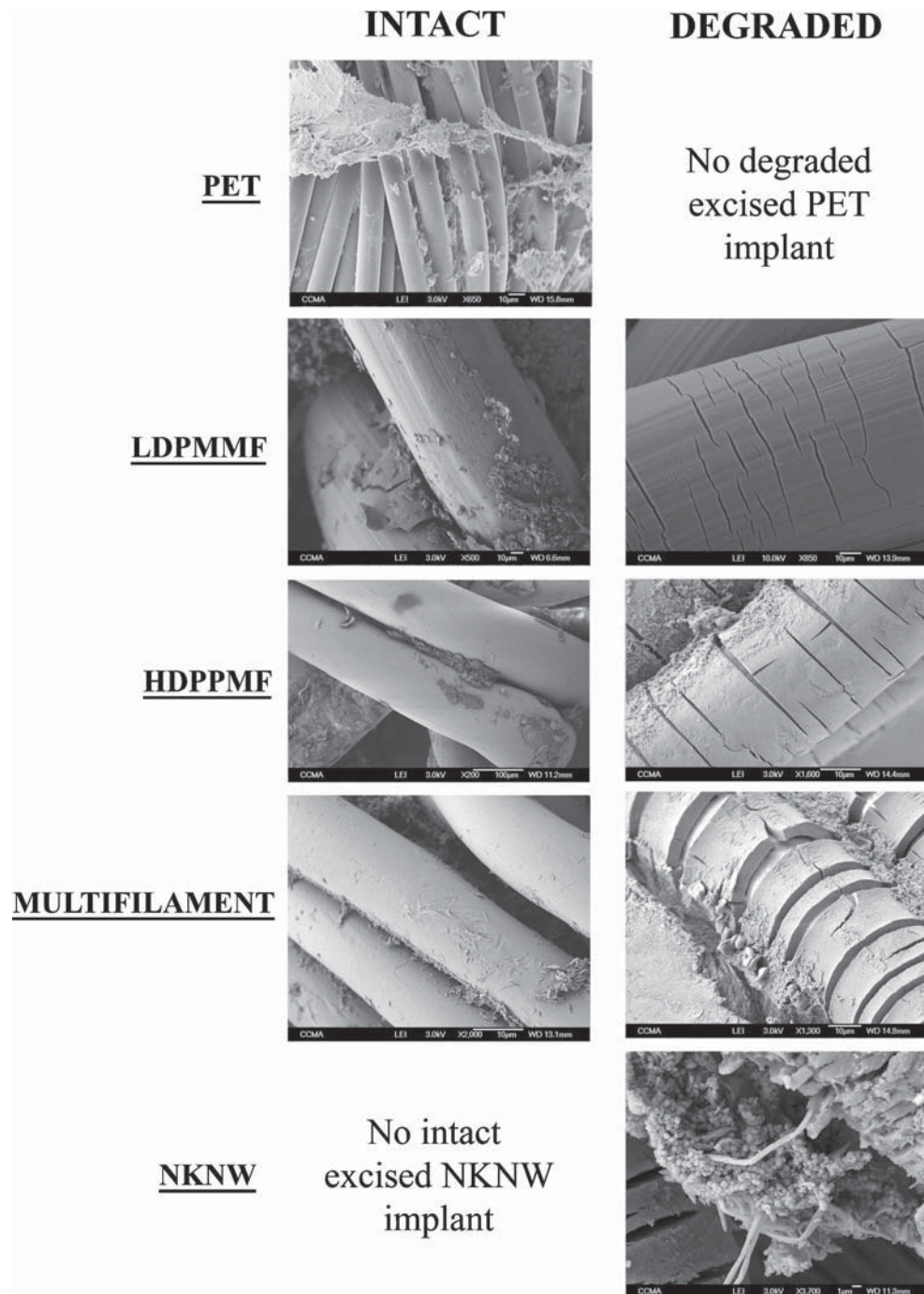
##### FTIR analysis

The FTIR spectra of explanted samples are shown in Fig. 4. The analysis results show that:

- The FTIR spectra of pristine Prolene® and Prolene Soft®, before and after the treatment with NaOCl and cyclohexane, were similar to typical FTIR spectra of PP reported in the literature (Fig. 4a). Therefore, the chemical treatment had little effect on the material.
- FTIR absorption bands between 1,615 and 1,650  $\text{cm}^{-1}$  could be attributed either to carboxylate carbonyl or to residual products of biological origin. Therefore, these results cannot confirm the formation of carboxyl groups in vivo.



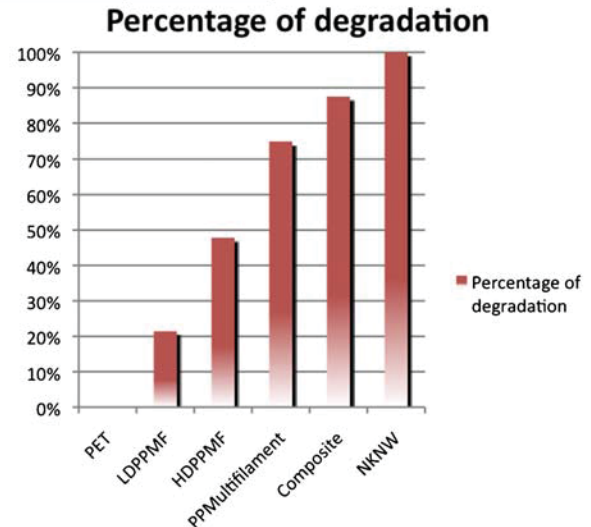
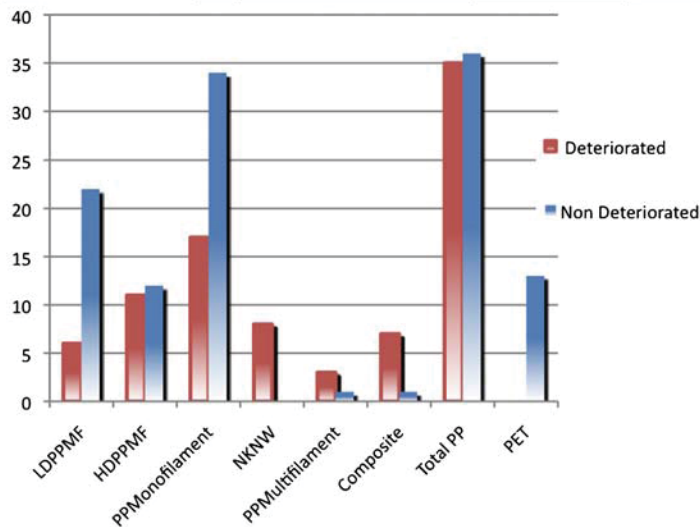
**Fig. 1** SEM comparison between intact and degraded explants



- The absorption band at  $1,730\text{ cm}^{-1}$  could correspond to the absorption of ester carbonyl groups, which is likely from esterified fatty acids. However, some samples of group 2 also showed that the absorption band at  $1,730\text{ cm}^{-1}$ , and they were not deemed damaged.
- The FTIR spectra of the PET sample after treatment revealed no change when compared to a typical PET spectrum. Therefore, the treatment had little effect on PET as well.

The DSC thermograms of treated degraded and non-degraded LDPPMF explants were similar to those of treated pristine Prolene Soft®. Additionally, the DSC thermograms of degraded and nondegraded HDPPMF explants were also similar to those of treated pristine Prolene® samples. No modification was observed in the melting temperature or heat of fusion of these samples. Thus, if an oxidation occurs in these prosthetics, it takes place in the amorphous zones, and crystallinity is preserved.

		Deteriorated	Non Deteriorated	Total	Percentage of degradation
		6	22	28	21,43%
<b>PolyPropylene</b>	<b>LDPPMF</b>	11	12	23	47,83%
	<b>HDPPMF</b>	17	34	51	33,33%
	<b>PPMonofilament</b>	8	0	8	100%
	<b>NKNW</b>	3	1	4	75%
	<b>PPMultifilament</b>	7	1	8	87,5%
	<b>Composite</b>	35	36	71	49,3%
<b>Total PP</b>					
<b>Polyester</b>	<b>PET</b>	0	13	13	0%



**Fig. 2** Morphological state of explants according to their nature: PP implants did not perform uniformly; PET implants are not deteriorated. **a** Summary table of the morphological state of the various explants. **b**

Deteriorated versus nondeteriorated explants (*X axis* categories of explants, *Y axis* number of explants). **c** Percentage of degradation according to the category

## Discussion

The primary objectives of this study were to objectively observe a series of prosthetic explants and to characterize potential degradation, which may occur in vivo.

Those histological, SEM, FTIR, and DSC analysis suggested the following:

- There are classifiable histological reactions observed in standard complications of pelvic surgery with prosthetic reinforcement.

Three types of tissue reactions were observed in this study. The correlation analysis between the prosthetics groups and tissue reaction types agreed with and supported those found in the literature: multifilament PP and NKNW implants seemed to present histological reactions of type 1 [14, 15]. The unexpected observation of types 1 and 2 reactions in LDPPMF and HDPPMF prostheses suggested that, contrary to expectations, the monofilament polypropylene prosthetics were not exempt from these complications.

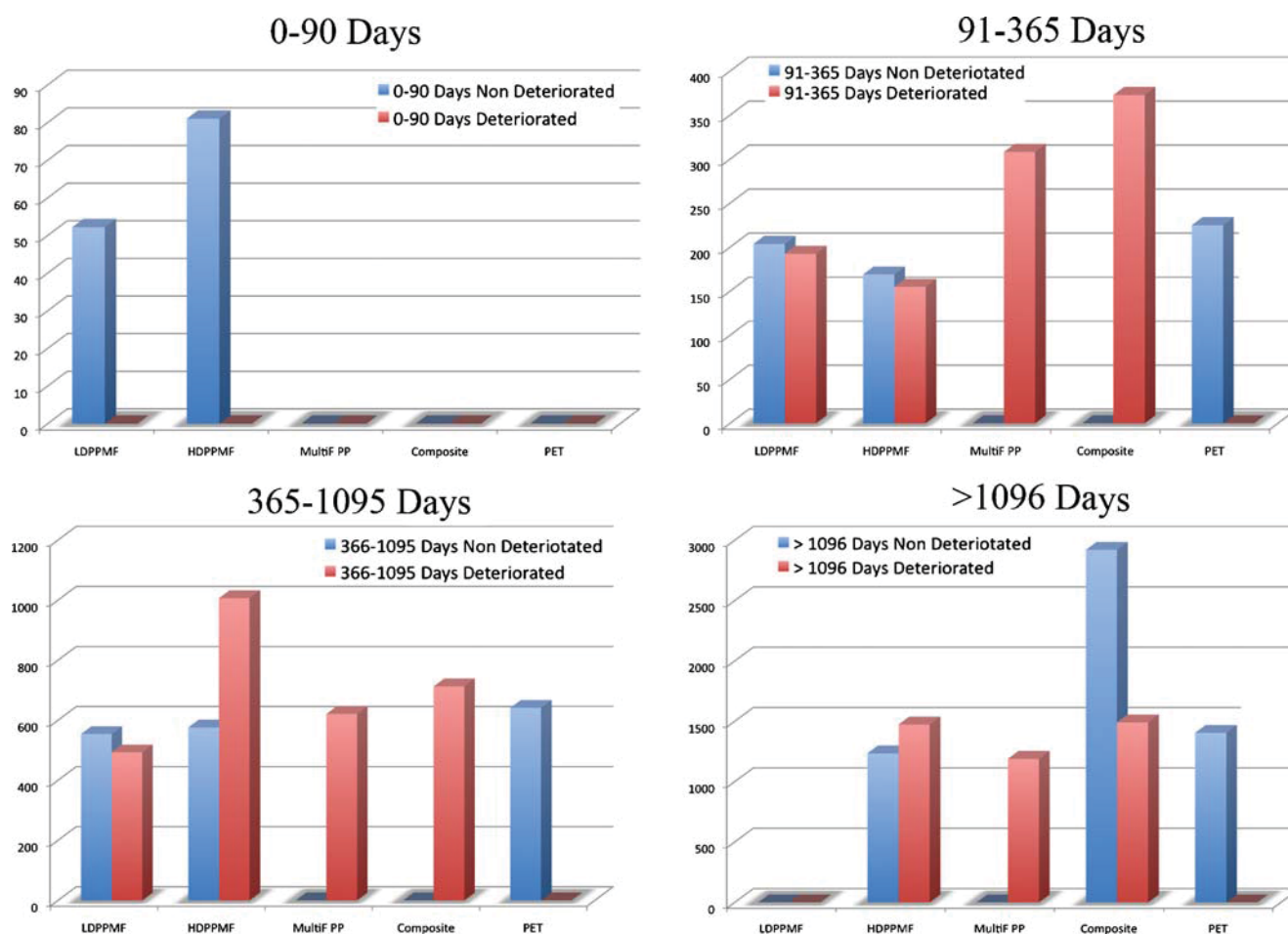
The type 1 reaction may correspond to an active debridement due to the presence of persistent pathogenic

agents in great quantities. Type 2 reaction may correspond to an incomplete debridement: the initial pathogenic agent may persist in tissues leading a succession of healing and debridement processes. This may explain the coexistence of partial prosthetic sheathing and the presence of polynuclear cells. Type 3 reaction may correspond to healing and aggravated foreign body reaction with an excessive collagen synthesis.

- PP implants are altered in vivo.

PP implants did not perform uniformly. The LDPPMF was least damaged, while 100% of the NKNW was damaged. Generally, it appeared that monofilament explants were more intact than multifilament explants. This was probably due to the more frequent infection in the NKNW group. The duration of implantation did not appear to correlate to the degree of damage for samples implanted more than 3 months. A significant correlation between type 1 and 2 reactions and all degraded polypropylenes were found.

Several hypotheses concerning the degradation of the PP are described below. None of these, particularly direct oxidation, could be confirmed in this study.



**Fig. 3** Deterioration of explants is not correlated to in vivo duration (*ND* nondeteriorated, *D* deteriorated, *X* axis categories of explants, *Y* axis number of explants)

i. Direct oxidation of the PP.

The in vivo oxidation of polypropylene implants has been reported in the literature. This oxidation should create carboxyl groups on the material [16, 17], which can be detected by FTIR analysis. The FTIR analysis neither confirmed nor excluded oxidation of PP in the in vivo environment.

ii. Fatty acid diffusion.

In previous works [18, 19], the authors suggested that the absorption band at  $1,730\text{ cm}^{-1}$  was related to cholesterol and esterified fatty acids that can diffuse in the amorphous zones of the polymer matrix. The diffusion of these organic molecules into the PP mesh filaments could affect the fiber physical and mechanical properties and generate the damage observed in some samples of group 1. Nevertheless, our study shows that some samples not showing evidence of degradation also absorb at  $1,730\text{ cm}^{-1}$ .

iii. Oxidation due to free radical attack; radical oxidation without formation of carboxyl groups.

The chronic inflammatory reaction may infer free radical synthesis as peroxide and superoxide ions and hypochlorite acid. Once in contact with the PP implant, these radical species could infer an oxidation of C-H bonds. This oxidation could occur in the absence of oxygen, and the resulting free radicals could recombine and cross-link, altering the physical and mechanical properties of the polymer. These cross-linking reactions could be the origin of the observed damage [20] without formation of carboxyl groups.

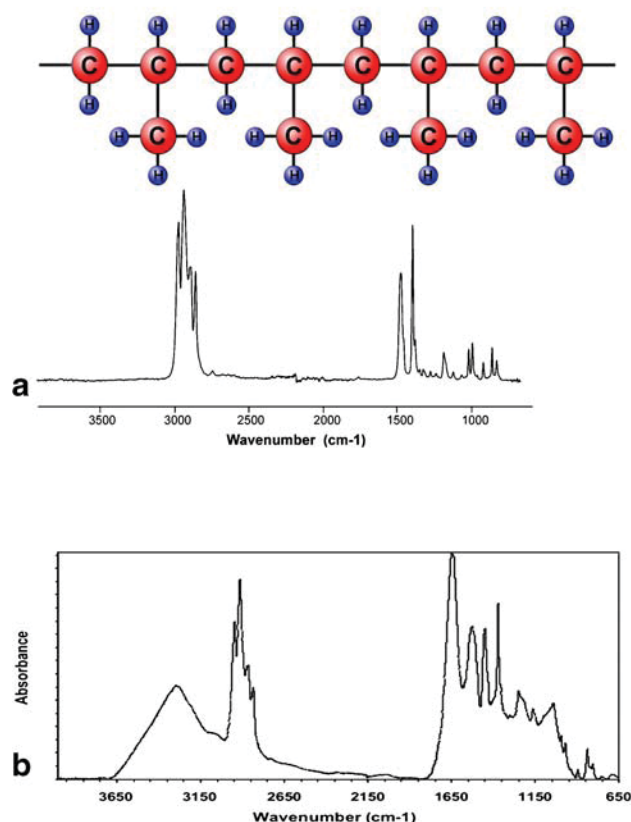
This hypothesis may explain the observed degradation occurring only for specimens implanted beyond 3 months: this time would correspond to the necessary period for oxidation to affect the PP structure. This explanation is enhanced by the significant correlation between the reactions of type 1 and 2 and the number of degraded PP samples found in this study.

c. There was no alteration of the PET implants.

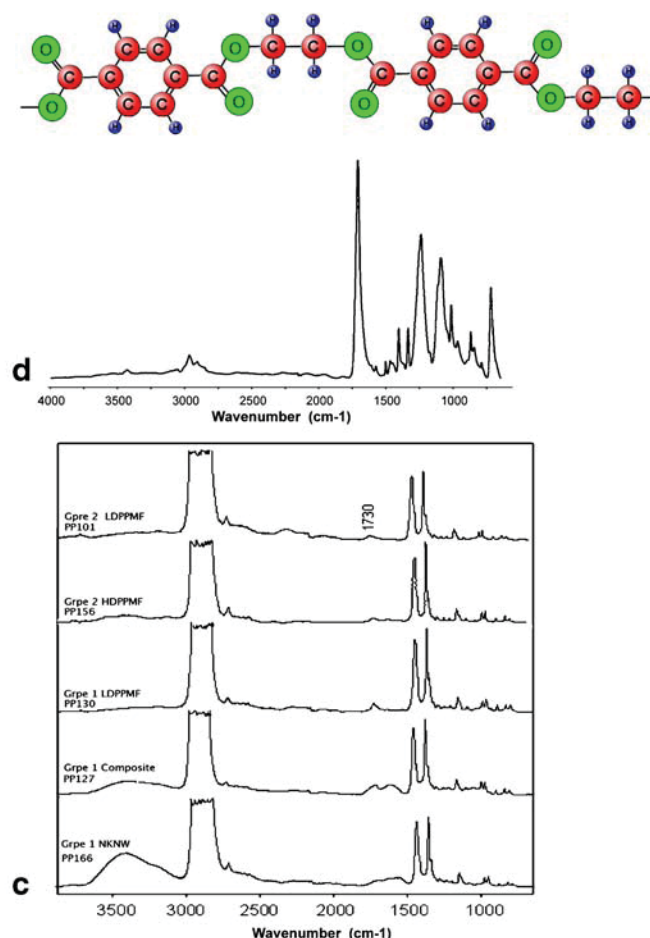
No alterations of PET were found with SEM analysis. The FTIR spectra of the PET samples after treatment



## Polypropylene



## Polyethylene terephthalate



**Fig. 4** FTIR Spectra of **a** typical PP spectrum and chemical structure, **b** representative FTIR spectrum of an excised PP sample before cleaning, **c** FTIR spectra of excised PP samples (group 1 and 2) after the cleaning procedure, and **d** typical PET spectrum and chemical structure

revealed no change when compared to a typical PET spectrum. The hydrophilic character of this polymer may limit the diffusion of the previously mentioned organic molecules. PET also appeared more stable regarding radical oxidation [19, 21].

Polypropylene, in particular, LDPPMF, is the most used material in the PFD surgery. It is generally considered an inert material [22]. This study contradicts this established fact and confirms the results of other studies on PP materials used in other areas of medical specialization.

A degradation related to the action of UV on PP threads used in ophthalmology has been described [23, 24]. In this study, the degradation of the polypropylene cannot be due to UV. More recently, studies were performed on the analysis of damage caused in implants, which were used in parietal surgery. These studies showed that PP meshes undergo degradation while in vivo, most likely due to fatty

acids diffusion [17] or oxidation with formation of carboxyl groups [19, 20]. The main argument for the later one was based on a difference in the thermal transitions, as measured by DSC, between pristine and degraded PP implants [18]. The author advised subsequent researchers to analyze specimens by FTIR for confirmation of the degradation hypothesis. In this study, no difference between DSC thermograms of pristine and degraded samples was found. Additionally, FTIR analysis did not conclusively confirm that the degradation was due to oxidation.

The septic environment and large detachments of the vaginal approach resulting in collection and bruising hematoma could support both the accumulation of fatty acids and an increased risk of infection and makes the environment for the synthetic implants significantly more challenging. In these conditions, it is possible that degradation of PP can occur from mechanisms different from those found, for example, in parietal surgery. In the same

way, it is possible that the PP degradation is due to the association of the various expressed mechanisms and not only to oxidation phenomena.

For obvious ethical reasons, this study did not provide the opportunity to analyze vaginal implants from non-pathological situation. Therefore, prediction of normal in vivo material aging or the range of consequences in the clinical state beyond the observed samples is not possible. Due to small effective sample size, it is not possible to categorically conclude on the basis of statistical analysis even if a clear tendency is present.

A study of mechanical properties and an estimation and comparison of the strength and resistance of the various explants was not possible due to individual specimen size, as well as the degraded state of the samples. Moreover, a full chemical analysis of every sample in this series of explants was not possible for these same reasons. Additional chemical analysis such as thermogravimetric analysis and molecular weight determination, specifically, would further clarify the mode of prosthetic damage.

## Conclusion

For transvaginal surgery, clinical experience indicates the use of low density, large pore implants knitted from a monofilament to facilitate tissue integration, and decrease the inflammatory reactions. This study, however, brings in to question the prevailing understanding of PP as inert when used in vaginal surgery for pelvic floor repair procedures.

In this work, not all types of PP implants degraded equally. The PP implants degraded more in the presence of an acute infection or chronic inflammation.

Several hypotheses persist concerning the nature of PP in vivo degradation. Large detachments and hematomas are one of the characteristics of the vaginal route and ultimately result in the massive accumulation of blood-derived fatty acids. The diffusion of organic molecules into the polymer (especially esterified fatty acids or cholesterol) may be a cause of the polymer structure degradation. Another explanation concerns radical oxidation due to the septic environment that accompanies acute infections and chronic inflammation. This results in an increase in free radicals generation. When radical oxidation occurs in the absence of oxygen, the formed radicals may promote cross-linking, which alters the physical and mechanical properties of the polymer.

PET exhibited greater resistance to radical oxidation. Additionally, the diffusion of nonpolar molecules such as esterified fatty acids or cholesterol appeared unfavorable. These properties may explain the stability of this polymer in the body. This preliminary study points to the need for clinical trials in order to comparatively investigate the performance of new types of monofilament meshes, such as

PET, to existing monofilament devices in various surgical applications.

**Acknowledgment** Many thanks to Jean-Pierre Laugier for his tremendous pedagogic work with SEM at the CCMA.

**Conflicts of interest** The work and research of H. Yahi were supported by a grant from SOFRADIM; S. Montanari is an affiliate of Covidien; Henri Clavé has an educational position for Ethicon Europe.

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# **EXHIBIT X**

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87 1989

**ETHICON, INC.**

a *Johnson & Johnson* company

SOMERVILLE NEW JERSEY 08876-0151

September 30, 1987

Dr. A. J. Melveger

cc: Dr. S. Garg  
Dr. R. Kronenthal  
Dr. A. Levy  
Mr. R. Lilenfeld  
Dr. J. McDivitt  
Mr. R. Morrissey  
Mr. F. Schiller  
RDCF

IR MICROSCOPY OF EXPLANTED PROLENE\*  
RECEIVED FROM PROF. R. GUIDOIN

-----

Samples of PROLENE\* suture carefully removed from human vascular graft explants received from Prof. R. Guidoin were examined by IR microscopy "as is". A PROLENE suture control was examined for comparison. The samples are described below:

<u>Sample</u>	<u>Implant Duration</u>	<u>Microscopy Observations (SEM- F. Schiller)</u>	<u>IR Spectra (Figure #)</u>
83D062 + 83TI9020	2 yr.	No cracking	1,2
83D035	8 yr.	Severe cracking	3,4,5,6,7
TB2418-Q Sterile Product	Non-implanted control	--	8,9

The samples were examined "as is" with no special preparation. Multiple spectra were obtained at different sites along the explants, especially for the 8-year severely cracked specimens. The IR spectra appear "bottomed out" since the sample thickness is quite significant.

Some samples of 83D035 (8 yr.) were examined optically. Using a needle, the cracked surfaces were easily wiped off and deposited on a KBr window. The surface "scrapings" had the handling and consistency of a waxy snow. The sample was not conducive to IR microscopy in this form however. Similar treatment with needles on sterile packaged PROLENE and the 2-year sample generated no scrapings.

ETHICON, INC.

\*Trademark

OCT 16 1987

RD-CENTRAL FILE

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The surface scrapings of 83D035 were melted at 147°-156°C on the Mettler hot stage. This is the melting range previously observed for oxidatively degraded polypropylene. IR microscopy of the melted film produced (Figures 10 & 11) yielded good spectra.

### Observations

Spectra of samples examined "as is" show remarkable similarity between explanted suture and unimplanted suture. All major polypropylene and pigment bands are observed (Figure 9). The 1740  $\text{cm}^{-1}$  band, seen strongest in the sterile product, is due to dilauryl thiodipropionate (DLTDP) additive. The DLTDP appears reduced in the 2-year sample spectra and further reduced in the 8-year sample spectra. DLTDP is not observed in the surface scraping spectra.

The observation of chemical species in the surface scrapings spectra of 83D035, yet not seen in the "bulk" spectra (surface + interior) of the suture explants, suggests that the regions affected by cracking or degradation are very small relative to the entire suture. The surface scraping spectra are very different from the "bulk" spectra, and both types of spectra show no evidence of the presence of protein.

The surface scrapings spectra of 83D035 clearly indicate polypropylene, but also three or four other broadened bands. Table I explains the possible functionalities determined from a library search of the IR bands not normally seen in polypropylene.

### Conclusions

The IR data collected for the PROLENE suture explant samples suggest:

1. The amount of DLTDP is reduced in the explanted sutures. No DLTDP is observed in the surface scraped (cracked regions) of 83D035. The observed DLTDP decreases with implant time.
2. No protein is observed in any spectra of the explanted sutures.
3. The surface scraped material from the cracked regions of 83D035 has a melting range indicative of degraded polypropylene. The IR spectra of this scraped material is clearly polypropylene, but it appears to be degraded in an oxidative fashion. There are a number of degradation species possible from the IR data. Hydroxyl and acid/ester functionality are definitely present. Ketone and/or unsaturated species are suggested, but not verified.
4. The degraded portion of the 8-year explant makes up only a minor portion of the entire suture.

  
D. F. Burkley

rmw  
Attachment  
1949N/93-95

# EXHIBIT Y

**ETHICON, INC.**  
a *Johnson & Johnson* company  
P.O. BOX 151  
SOMERVILLE • NEW JERSEY • 08878-0151

October 15, 1992

cc: B. Matlaga  
J. McDivitt  
↓  
A. Melveger  
RDCF

Mark Cafone

SEVEN YEAR DATA FOR TEN YEAR PROLENE™ STUDY: ERF 85-219  
-----

This report contains a summary of IR, IV, GPC, OM and SEM data supporting this study.

**IR and IR Microspectroscopy (D.Burkley)**

IR examinations were done for all explants at all sites to verify the suture identity for each explant. For all explanted sutures recovered from all 6 sites for every dog in this study, IR data showed each suture to be correctly identified.

IR microspectroscopy was used to examine cracked areas in ETHILON, Novafil and PROLENE™ explants. IR spectra obtained for cracked PROLENE specimens (Figure A) showed possible evidence of slight oxidation (a broadened weak absorbance at about 1650 cm<sup>-1</sup>). IR spectra obtained for cracked areas of ETHILON and Novafil did not differ from uncracked areas (Figures B and C), but expected IR absorbances for oxidation would be masked by the strong carbonyl absorbances normally observed for these sutures. Figures D and E show pictures of the areas examined by IR microspectroscopy for ETHILON and Novafil.

**IV and GPC (E.Muse)**

Gel Permeation Chromatography (GPC) was run on PROLENE sutures explanted from dogs after seven years. The GPC data was compared to data from a current 4/0 PROLENE suture. The results indicate that there was no significant difference in molecular weight between the 4/0 PROLENE control and the seven year explants.

The following PROLENE explant samples were analyzed:

Dog 1995 - site 3 (SR33853)  
Dog 2007 - sites 1 and 6 (SR34003)  
Dog 2008 - site 2 (SR34066)  
Dog 2019 - sites 2 and 3 (SR34180)

The GPC analysis was run on the Waters 150C GPC at 140°C using 1,2,4 trichlorobenzene as a mobile phase with Waters GPC columns. The instrument was calibrated with polypropylene standards.



Inherent Viscosity (IV) was determined on ETHILON<sup>™</sup> and Novafil sutures explanted from dogs after seven years. The IV data<sup>1</sup> was compared to IV data from one and two year explants. The following results were found:

- 1) No significant differences were seen in IV values after one and two years.
- 2) Seven year IV values ranged from 75% to 93% of the one and two year IV values for ETHILON sutures.
- 3) Seven year IV values ranged from 75% to 90% of the one and two year values for Novafil.

The dog explant samples examined were from duplicate sites on four dogs for each time period (one, two and seven years). The IV data was determined using concentrations of 0.1 dl/g with HFIP as a solvent at 25°C.

#### OPTICAL MICROSCOPY and SCANNING ELECTRON MICROSCOPY (E.Lindemann)

##### Conclusions

- The 7 year in-vivo results generally substantiated the five year findings. They also closely correspond to the observations of explanted sutures from the dog that died prematurely after 6 years and 10.5 month implantation time.
- Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking.
- Of the eight explanted ETHILON sutures all showed heavy cracking and, in many cases, abrasion of the dyed surface layer. A decrease in the suture diameter was apparent in several cases.
- Cracks were not found in the seven Novafil explants. However a few longitudinal scratches probably due to mechanical damage and one longitudinal crack were observed.

##### Introduction

In November 1985 twenty-four dogs had been implanted with sets of ETHILON, PROLENE, PVDF and Novafil sutures for a ten year study. In 1990, after five years, explants from 5 beagle dogs were described in "TEN YEAR IN-VIVO STUDY SCANNING ELECTRON MICROSCOPY FIVE YEAR REPORT" by Elke Lindemann. The next explantation, after 7 years, was to start in June 1992. However, after 6 years and 10.5 months dog #1995 died prematurely. The microscopical examination of those explants was described in "TEN YEAR IN-VIVO STUDY: SCANNING ELECTRON AND LIGHT MICROSCOPY INTERIM REPORT ON DOG #1995 AFTER 6 YEARS, 10.5 MONTH, SR# 33788 and are included in the conclusion section of this report. In June of 1992 after 7 years, sutures were explanted from another set of 4 dogs. This report presents the results of the light and scanning electron microscopical examination of those explants.

---

<sup>1</sup>SR33853, SR34003, SR34066, SR34180

**Experimental**

Four dogs had been implanted in November 1985 with the following 5-0 sutures:

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
Dog 2001	PVDF	ETHILON	Novafil	PROLENE	PROLENE	Novafil
Dog 2007	PROLENE	Novafil	ETHILON	PVDF	PVDF	PROLENE
Dog 2019	Novafil	PROLENE	PROLENE	PVDF	ETHILON	ETHILON
Dog 2008	ETHILON	PROLENE	Novafil	PVDF	ETHILON	PVDF

Starting in June of this year the above dogs were sacrificed in weekly intervals. Approximately 20cm long sections of the explanted sutures were received in microscopy in glass vials which were kept refrigerated until they were examined.

Also the explanted LC 100 clip with about 2cm of each suture bundle was delivered in the same vial. The clip and the attached sutures were still deeply embedded in the surrounding tissue. These 'not cleaned' sutures were supposed to answer the question whether the process of cleaning and tissue removal might be responsible for an observed cracking. The primary concern of this study was however to examine the long pieces of explanted suture. Most of these specimens were still surrounded with some tissue, fortunately at a level low enough not to obscure examination in the light microscope under transmitted light. It was possible to examine the embedded PROLENE suture where the cracking of the suture was seen through the tissue. For this reason and time constrains the clip-attached sutures were not examined at this time.

To show that the drying and coating with a metal under vacuum, necessary for SEM examination, did not introduce cracking and other surface defects each strand of each long suture was 100% inspected in the Olympus Light Microscope in water. Oil, the usual medium for light microscopical inspection, was not chosen for this examination in order to eliminate surface changes during sample preparation. To cut down on lensing effects of the curved suture, the samples were photographed in polarized light using a 10x phase condenser with an ordinary transmitted light 20x objective (a 20x phase condenser was not available). The light diffraction introduced by the phase condenser was enough to allow an easier focusing at the focal plane of the largest diameter. Photomicrographs were prepared at 285x of areas which showed surface changes.

Strands of the suture including the above areas were then prepared for SEM observation in the JEOL JSM 840 AII by coating them under vacuum with gold to provide an electron conductive surface. Photomicrographs were prepared at 500x magnification.

**Results****1) LM and SEM of PROLENE suture explants from seven implantation site.**

In Figure 1A through 1D one area per site from each of the four dogs is shown in transmitted light. Out of seven sites cracking was found on PROLENE sutures from three sites. Notice the cracks observable through the still adhering tissue in Figure 1A in the suture from site 2.

In Figure 1 and 2 SEM views of areas are shown after most of the tissue had been carefully removed. Again out of seven sites sutures from three sites had areas which showed cracking.

**2) LM and SEM of ETHILON suture explants from six implantation sites.**

In Figure 3A through 3C sutures are shown from six different sites. Transmitted light allowed visualization of the differences between the intact dyed surface layer and the underlying colorless layers of the suture. In Figure 3A site 5 and Figure 3C site 3 the colorless area had not only lost its dyed surface layer but was abraded to such a degree that a decrease in suture diameter was found.

In Figures 3 and 4 the cracking and abrasion on sutures from all six sites, as observed with the SEM, is shown. Here also the decrease in diameter is particularly dramatic in Figure 3 site 1.

**3) LM and SEM of PVDF suture explants from six implantation sites.**

Figure 5A through 5C show six sites of PVDF explants as seen with the light microscope. Notice the intact surface on all the sutures.

In Figures 5 and 6 the SEM examination of the PVDF sutures is shown. Only on the suture from one site (Figure 6 site 6) some cracks are found. The surfaces of the sutures from the other five sites show some striations which could be mechanical damage, otherwise the surfaces look intact. The contaminant on the site 4 (Figure 5) suture is tissue which had not been removed completely.

**4) LM and SEM of Novafil suture explants from five implantation sites.**

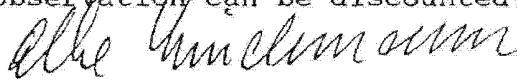
Figure 7A through 7C show the Novafil sutures as observed with the light microscope. All surfaces from all sites look undamaged. Figure 7 and 8 show the SEM examination of these sutures. A few longitudinal scratches and cracks were found, see sites 1,2,3 (Figure 7,8). Also on the site 2 suture (Figure 8) still adhering tissue is found.

**5) Degradation dependency on implantation site**

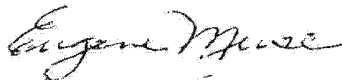
To probe the question as to whether one implantation site might be more or less stressful towards the suture, a comparison was made of the six sites.

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
Dog 1995	ETHILON cracks	PVDF	PROLENE cracks	Novafil	Novafil cracks	ETHILON cracks
Dog 2001	PVDF	ETHILON cracks	Novafil	PROLENE	PROLENE cracks	Novafil
Dog 2007	PROLENE	Novafil scratch	ETHILON cracks	PVDF	PVDF	PROLENE cracks
Dog 2019	Novafil scratch	PROLENE	PROLENE	PVDF	ETHILON cracks	ETHILON cracks
Dog 2008	ETHILON cracks	PROLENE cracks	Novafil cracks	PVDF	ETHILON cracks	PVDF cracks

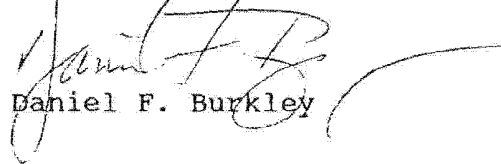
The only site, in the 5 dogs of this study, from which sutures were explanted that showed no surface damage was site 4. However, of those five sutures three were PVDF and one was Novafil. Those are the sutures that showed only marginal surface changes in this study. Therefore this observation can be discounted.



Elke Lindemann



Eugene P. Muse



Daniel F. Burkley

Attachment

7YEAR.DFB

# **EXHIBIT Z**



Howard C. Jordi, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION  
Master File No. 2:12-MD-02327

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IN RE: ETHICON, INC. MDL No. 2327  
PELVIC REPAIR SYSTEM,  
PRODUCTS LIABILITY  
LITIGATION

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This Document Relates to:

Carolyn Lewis, Et Al v. Ethicon, Inc.  
Case No. 2:12-CV-04301

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IN THE DISTRICT COURT, 95th JUDICIAL DISTRICT  
DALLAS COUNTY, TEXAS

Linda Batiste,  
Plaintiff,

v.

John Robert McNabb, M.D.,  
Johnson & Johnson and Ethicon, Inc.,  
Defendants.

Cause No.  
DC-12-14350

---

DEPOSITION OF HOWARD C. JORDI, Ph.D.

Wednesday, October 30th, 2013

9:05 a.m.

Held At:

Jordi Lab  
200 Gilbert Street  
Mansfield, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RPR, CLR, CSR #149108



Howard C. Jordi, Ph.D.

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<p>1 APPEARANCES:</p> <p>2 FOR THE PLAINTIFFS:</p> <p>3 BY: BENJAMIN H. ANDERSON, ESQ.</p> <p>4 ANDERSON LAW OFFICES, LLC</p> <p>5 1360 West 9th Street, Suite 215</p> <p>6 Cleveland, Ohio 44113</p> <p>7 216-589-0256</p> <p>8 ben@andersonlawoffices.com</p> <p>9 -and-</p> <p>10 BY: DANIEL J. THORNBURGH, ESQ.</p> <p>11 AYLSTOCK, WITKIN, KREIS &amp; OVERHOLTZ PLLC</p> <p>12 17 East Main Street, Suite 200</p> <p>13 Pensacola, Florida 32502</p> <p>14 850-202-1010</p> <p>15 dthornburgh@awkolaw.com</p> <p>16</p> <p>17 FOR THE DEFENDANTS ETHICON, INC., and JOHNSON &amp;</p> <p>18 JOHNSON:</p> <p>19 BY: DAVID B. THOMAS, ESQ.</p> <p>20 THOMAS COMBS &amp; SPANN, PLLC</p> <p>21 300 Summers Street, Suite 1380</p> <p>22 Charleston, West Virginia 25301</p> <p>23 304-414-1807</p> <p>24 dthomas@tcspllc.com</p> <p>25</p>	<p>1 INDEX</p> <p>2 EXAMINATION PAGE</p> <p>3 HOWARD C. JORDI, Ph.D.</p> <p>4 BY MR. THOMAS 5</p> <p>5 BY MR. ANDERSON 286</p> <p>6 EXHIBITS</p> <p>7 NO. DESCRIPTION PAGE</p> <p>8 1 Rule 26 Expert Report of Howard</p> <p>9 Jordi, PhD in the Carolyn Lewis</p> <p>10 case..... 6</p> <p>11 2 Document titled Final Report, Linda</p> <p>12 Batiste..... 7</p> <p>13 3 De Tayrac and Letouzey article</p> <p>14 titled "Basic science and clinical</p> <p>15 aspects of mesh infection in pelvic</p> <p>16 floor reconstructive surgery..... 54</p> <p>17 4 Liebert, et al study titled</p> <p>18 Subcutaneous Implants of</p> <p>19 Polypropylene Filaments..... 72</p> <p>20 5 Group of invoices from Jordi Labs....183</p> <p>21 6 10/30/13 Final Report for Linda</p> <p>22 Batiste.....209</p> <p>23 7 Group of films.....267</p> <p>24</p> <p>25</p>
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<p>1 APPEARANCES VIA SPEAKERPHONE</p> <p>2 FOR THE PLAINTIFF CAROLYN LEWIS:</p> <p>3 BY: CALLE M. MENDENHALL, ESQ.</p> <p>4 FREESE &amp; GOSS PLLC</p> <p>5 Regions Harbert Plaza 1901</p> <p>6 6th Avenue North</p> <p>7 Birmingham, Alabama 35203</p> <p>8 205-871-4144</p> <p>9 calle@freeseandgoss.com</p> <p>10</p> <p>11 FOR DEFENDANT DR. JOHN McNABB in the Batiste</p> <p>12 case:</p> <p>13 BY: PHILIPA M. REMINGTON, ESQ. (AM)</p> <p>14 CHARLES A. ESTEE, ESQ. (PM)</p> <p>15 THIEBAUD, REMINGTON, THORNTON, BAILEY, LLP</p> <p>16 1445 Ross Avenue, Suite 4800</p> <p>17 Dallas, Texas 75202</p> <p>18 214-954-2210</p> <p>19 premington@trtblaw.com</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 PROCEEDINGS</p> <p>2</p> <p>3 HOWARD C. JORDI, Ph.D.,</p> <p>4 having been first duly identified and sworn, was</p> <p>5 examined and testified as follows:</p> <p>6 DIRECT EXAMINATION</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Good morning, Dr. Jordi.</p> <p>9 A. Good morning.</p> <p>10 Q. I introduced myself to you before the</p> <p>11 deposition. My name is David Thomas, and I</p> <p>12 represent the Defendants in the case. And I'm</p> <p>13 going to take your deposition in two matters,</p> <p>14 the Carolyn Lewis matter and the Batiste case</p> <p>15 from Texas.</p> <p>16 You understand that?</p> <p>17 A. I do.</p> <p>18 Q. We're here in your offices in</p> <p>19 Massachusetts?</p> <p>20 A. Yes, we are.</p> <p>21 Q. And is Massachusetts your home?</p> <p>22 A. It is.</p> <p>23 Q. Okay. Would you state your full name</p> <p>24 for the record, please?</p> <p>25 A. Howard Craig Jordi.</p>

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<p>1 Q. And you're a Dr. Jordi, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. A Ph.D doctor?</p> <p>4 A. A Ph.D doctor.</p> <p>5 Q. Not a medical doctor?</p> <p>6 A. Not a medical doctor.</p> <p>7 Q. And in what area is your Ph.D?</p> <p>8 A. Biochemistry.</p> <p>9 Q. What is a biochemist?</p> <p>10 A. A biochemist is one who studies the</p> <p>11 reactions of chemicals in the body.</p> <p>12 Q. Okay. Dr. Jordi, I've been provided</p> <p>13 two reports in this case. I'm going to mark as</p> <p>14 deposition Exhibit Number 1 what's been provided</p> <p>15 to me as your Rule 26 expert report of Howard</p> <p>16 Jordi, Ph.D in the Carolyn Lewis case.</p> <p>17 A. Okay.</p> <p>18 (Whereupon, Jordi Exhibit Number 1,</p> <p>19 Rule 26 Expert Report of Howard Jordi,</p> <p>20 PhD in the Carolyn Lewis case, was</p> <p>21 marked for identification.)</p> <p>22 MR. THOMAS: And I'm going to mark as</p> <p>23 Exhibit Number 2 what's been provided to me as a</p> <p>24 document titled Final Report for Linda Batiste.</p> <p>25</p>	<p>1 final, rather than looking at each and every</p> <p>2 page, he's trying to do the best he can in the</p> <p>3 interest of time.</p> <p>4 MR. THOMAS: It's 847 pages, and I'll</p> <p>5 represent to you that we copied it as best we</p> <p>6 could and produced it for him, and I'm just</p> <p>7 trying to get him to identify it as best he can.</p> <p>8 MR. ANDERSON: So stipulated.</p> <p>9 MR. THOMAS: The Batiste report is</p> <p>10 some 240 pages, and I don't expect him to go</p> <p>11 through every page, unless he wants to. But</p> <p>12 I'll represent that's a copy of what was</p> <p>13 supplied to me.</p> <p>14 MR. ANDERSON: Right.</p> <p>15 MR. THOMAS: I'm trying to just get it</p> <p>16 identified as best we can.</p> <p>17 MR. ANDERSON: Right. I'm just saying</p> <p>18 he's leafing through it to do the best he can</p> <p>19 without taking every page and looking at it in</p> <p>20 detail.</p> <p>21 A. It appears to be complete.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Okay. Dr. Jordi, how do you charge</p> <p>24 for your time?</p> <p>25 A. I bill hourly.</p>
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<p>1 (Whereupon, Jordi Exhibit Number 2,</p> <p>2 Document titled Final Report, Linda</p> <p>3 Batiste, was marked for</p> <p>4 identification.)</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Okay. And let me tell you what I did.</p> <p>7 Those are double-sided copies because I didn't</p> <p>8 care to --</p> <p>9 A. I was going to say it didn't seem</p> <p>10 thick enough.</p> <p>11 Q. It's half as thick as you expected it</p> <p>12 to be.</p> <p>13 A. Yes.</p> <p>14 Q. Because I didn't care to carry all</p> <p>15 those papers with me. These are the documents</p> <p>16 that were provided by counsel in the case.</p> <p>17 Can you review those quickly, or as</p> <p>18 much time as you need, and confirm for me that</p> <p>19 those are complete copies of your expert reports</p> <p>20 in the case?</p> <p>21 (Witness reviewing documents.)</p> <p>22 MR. ANDERSON: I'd just like for the</p> <p>23 record to reflect that it's an almost 800 page</p> <p>24 report, and he's trying to leaf through it as</p> <p>25 best he can and to try to determine if it's</p>	<p>1 Q. And what is your hourly rate?</p> <p>2 A. 350 an hour.</p> <p>3 Q. Is your hourly rate the same for</p> <p>4 whatever work that you do?</p> <p>5 A. Yes.</p> <p>6 Q. Have you calculated the total amount</p> <p>7 dollars that you've billed for Exhibit 1, the</p> <p>8 Lewis report?</p> <p>9 A. We'd have to look at the receipts, the</p> <p>10 billings for that.</p> <p>11 Q. Do you have those with you today?</p> <p>12 A. I believe we do.</p> <p>13 MR. ANDERSON: Yes.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. And the same for the Batiste matter?</p> <p>16 A. Same.</p> <p>17 MR. THOMAS: Okay. Ben, we'll come</p> <p>18 back to that in a few minutes.</p> <p>19 MR. ANDERSON: Sure.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Those billing records are readily</p> <p>22 available, and you can determine how much it</p> <p>23 cost you to produce Exhibit 1, the report in</p> <p>24 Carolyn Lewis, and Exhibit 2, the report for</p> <p>25 Linda Batiste?</p>

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<p>1 A. I don't know if this has been billed</p> <p>2 yet, but this one should be. I think we bill</p> <p>3 monthly, so it hasn't gone out yet.</p> <p>4 Q. When you say "this one," you're</p> <p>5 referring to Exhibit 2, which is Linda Batiste?</p> <p>6 A. Yes, sir.</p> <p>7 Q. Okay. And do you have records that</p> <p>8 you'd be able to get sometime during the day so</p> <p>9 that I can tell how much time you have into it</p> <p>10 that hasn't been billed so I know how much cost</p> <p>11 there was for the Linda Batiste report?</p> <p>12 MR. ANDERSON: I might be able to help</p> <p>13 you. In response to your notice of subpoena,</p> <p>14 the 21 categories, we did our best to try to</p> <p>15 respond to those, the ones that we thought he</p> <p>16 could respond to, and as part of that we tried</p> <p>17 to get as up to date a billing as we could for</p> <p>18 you, and that would include as much of Batiste</p> <p>19 as possible, at least up until last week.</p> <p>20 MR. THOMAS: Okay.</p> <p>21 MR. ANDERSON: So that's -- we've</p> <p>22 tried. And I think that you'll be able to look</p> <p>23 at it, and from the dates be able to tell</p> <p>24 whether or not it includes anything this week or</p> <p>25 not.</p>	<p>1 Q. All right. Do you understand that</p> <p>2 there are different products that are at issue</p> <p>3 in the Lewis case and the Batiste case?</p> <p>4 MR. ANDERSON: Objection.</p> <p>5 Go ahead.</p> <p>6 A. The samples that I received I just</p> <p>7 received and ran by identification numbers</p> <p>8 without regards to -- certainly the pristine</p> <p>9 materials were identified.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Okay. Do you have any knowledge --</p> <p>12 what I'm trying to get at, Doctor, is, I'll</p> <p>13 represent to you, my understanding anyway, is</p> <p>14 the Carolyn Lewis case involves a product known</p> <p>15 as a TVT Classic or a TVT Retropubic, and the</p> <p>16 Batiste case, Exhibit Number 2, I understand,</p> <p>17 involves a product known as a TVT Obturator or</p> <p>18 TVT-O.</p> <p>19 Do you know that?</p> <p>20 A. No. That wasn't represented to us, as</p> <p>21 far as I'm concerned.</p> <p>22 Q. As far as you're concerned --</p> <p>23 A. It's an explant.</p> <p>24 Q. Okay. In the work that you did in</p> <p>25 these matters, does it concern you at all</p>
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<p>1 MR. THOMAS: Perfect.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. For the Carolyn Lewis case, your final</p> <p>4 report in Exhibit Number 1, is that a complete</p> <p>5 copy of the report of the opinions that you</p> <p>6 intend to give in the Carolyn Lewis case?</p> <p>7 A. It is.</p> <p>8 Q. Do you have any intention of doing any</p> <p>9 additional work prior to testifying in trial in</p> <p>10 this case in connection with new opinions for</p> <p>11 the Carolyn Lewis case?</p> <p>12 MR. ANDERSON: I'm just going to</p> <p>13 object, because as counsel knows, we have a</p> <p>14 right to do rebuttal reports in this case, so he</p> <p>15 may not even understand that. And so with that</p> <p>16 caveat, that as he sits here today.</p> <p>17 A. To my knowledge, this is complete, and</p> <p>18 this is what I will be using.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Same question with respect to Linda</p> <p>21 Batiste, Exhibit Number 2; does Exhibit Number 2</p> <p>22 represent a complete report of the opinions that</p> <p>23 you're prepared to give in the Linda Batiste</p> <p>24 case?</p> <p>25 A. Yes.</p>	<p>1 whether this is a TVT Classic or a TVT Obturator</p> <p>2 or a TVT Retropubic or TVT-O?</p> <p>3 A. No. They're all polypropylene, and in</p> <p>4 that sense, for that reason, no.</p> <p>5 Q. Is it fair to understand, Doctor --</p> <p>6 just trying to do something to make this easier,</p> <p>7 believe it or not -- is it fair to understand,</p> <p>8 Doctor, that the work that you did in analyzing</p> <p>9 the mesh explants and the mesh controls that's</p> <p>10 represented in Exhibit Number 1 and Exhibit</p> <p>11 Number 2 do not depend on the type of product</p> <p>12 that you were analyzing?</p> <p>13 MR. ANDERSON: Objection.</p> <p>14 Go ahead.</p> <p>15 A. As a polymer chemist and having</p> <p>16 studied polypropylene, among others, for my</p> <p>17 lifetime of work, basically polypropylene is</p> <p>18 polypropylene is polypropylene, so it's going</p> <p>19 to -- if it's polypropylene it's going to have</p> <p>20 the characteristic reactions of polypropylene.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q. Did the work that you did for Exhibit</p> <p>23 Number 1 differ from the work that you did in</p> <p>24 Exhibit Number 2 because of the name of the</p> <p>25 product that was analyzed in each case?</p>

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<p>1 A. Did not. 2 I'm sorry. 3 MR. ANDERSON: Go ahead. That's fine. 4 BY MR. THOMAS: 5 Q. And what were you trying to do when 6 you -- what were you asked to do in Exhibit 7 Number 1? 8 A. We were asked to compare pristine mesh 9 samples and explant samples and determine 10 whether or not there were differences; and if 11 there were, what they were. 12 Q. What did you understand to be the 13 differences that you were looking for? 14 A. I wasn't told to look for any specific 15 differences. I was told to look for 16 differences, if there were any. 17 Q. And how did you set out to determine 18 whether there were differences between the 19 explants and the pristine samples that you'd 20 received? 21 A. Given the knowledge that it was 22 polypropylene, classic tests that we would 23 typically run on any polypropylene would be 24 molecular weight, to see if it degraded in terms 25 of its molecular weight.</p>	<p>1 BY MR. THOMAS: 2 Q. Absolutely. 3 A. Do I need to reference this one, 4 because it's not marked? 5 MR. ANDERSON: You can look at 6 anything. 7 A. It's this. I just want to make sure I 8 have all of the techniques referenced here that 9 I did. 10 We did optical microscopy as well to 11 see if there were any obvious differences, and 12 to just look at the shape of the fibers. 13 GPC. I think we got them all. 14 MR. ANDERSON: Did you say GPC? 15 A. Gel permeation chromatography. GPC 16 for molecular weight. 17 BY MR. THOMAS: 18 Q. How did you determine what tests to 19 conduct on the mesh that you analyzed in Exhibit 20 Number 1? 21 A. I've analyzed these kinds of materials 22 since 1980. In this particular business we 23 built -- I founded this company, and so it's 24 just years and years of experience. 25 Polypropylene has to be stabilized because it's</p>
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<p>1 We would look for additive content, 2 because that stabilizes polypropylene. 3 How am I doing speed-wise? 4 So we did additives analysis. 5 We would do DSC to look for 6 crystallinity. 7 We did SEM to look for cracks. 8 We did SEM-EDX to look for elemental 9 composition. Specifically we were looking for 10 differing oxygen levels which would indicate and 11 correlate with oxidation, if present. 12 We did FTIR analysis to look for 13 presence of carbonyls. And we specifically 14 there wanted to find out whether the flaking 15 material, once we saw it from the SEM, was 16 polypropylene or not, what was the composition, 17 chemical composition of the flakes that were 18 coming off the polypropylene fibers. I'm trying 19 to think. 20 So we also ran PYMS. That's another 21 technique to look for additives, presence of 22 additives. 23 I need to -- 24 MR. ANDERSON: Do you want to 25 reference your report?</p>	<p>1 a reactive polymer. That information goes back 2 at least to the '60s. So you've got to look for 3 the antioxidants, the presence or lack thereof. 4 GPC is to determine the molecular weight, as I 5 said. DSC is to determine the melt point and 6 the FLP at melt, which correlates with percent 7 crystallinity. SEM is a means of looking at the 8 physical shape of the fibers. So these are just 9 standard techniques that we used. So we chose 10 standard techniques that I would use for any 11 such type of analysis. 12 Q. Type of such analysis, what do you 13 mean by that? 14 A. Well, in our company we analyze any 15 kind of polymer. So we analyze polystyrene one 16 day, we analyze contact lens materials another 17 day, we analyze polypropylene, some of which 18 have been implanted in the human bodies, hips 19 and so on on another day. You could really call 20 us a materials lab. 21 Q. Okay. What I'm trying to understand 22 is when you got this request from Mr. Anderson 23 and his associates and they asked you to analyze 24 this polypropylene material both as an explant 25 and as a pristine sample, did you go to the</p>

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<p>1 shelf and pull off a list and say "I'm going to 2 do this list of tests"?</p> <p>3 A. No, because I already knew it from 4 experience.</p> <p>5 Q. Okay.</p> <p>6 A. We would do this type of work for any 7 client.</p> <p>8 Q. So the tests that you identified for 9 purposes of your report in both Exhibits 1 and 10 Exhibits 2 are based upon your training, 11 education, and experience, as opposed to any 12 reference guide that you may have looked to to 13 determine what tests you may have run, is that 14 fair?</p> <p>15 A. Well, I have reference guides. I mean 16 I have books. I do continue to -- reading is an 17 ongoing learning technique I continue to use, 18 and always will.</p> <p>19 Q. Sure.</p> <p>20 A. But no, I wouldn't need to read those 21 books to pop up with the techniques because 22 they're standard in the industry.</p> <p>23 Q. Is there a place where I could go 24 to -- if they came to me and said "Mr. Thomas, I 25 want to have these polypropylene tests run on</p>	<p>1 Engineers, yes.</p> <p>2 Q. And for what purpose do you cite 3 Dr. Müller, is that the additives analysis?</p> <p>4 A. There would be additives analysis, 5 stabilization of various polymers, polypropylene 6 being one of them.</p> <p>7 Q. Are there any other texts or 8 authorities upon which you rely to identify the 9 tests that you need to contact on the explants 10 and the pristine samples?</p> <p>11 A. To identify the tests needed?</p> <p>12 Q. Yes.</p> <p>13 A. Well, reading 400 pages of literature, 14 and part of it is just the body of knowledge 15 that you get from reading all of the literature. 16 Everyone in the last -- starting back -- going 17 back to the '60s has used these techniques.</p> <p>18 Q. Okay.</p> <p>19 A. Some of them, of course, are more 20 modern today, obviously, than they were in the 21 '60s. Today we have available FTIR microscopy, 22 which we can look at a tiny sample. We didn't 23 have that available then. LCMS didn't exist in 24 the '70s and '60s, does now. So some of these 25 techniques have come along in terms of</p>
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<p>1 this pristine control and this explant, what 2 tests should I run?" Is there a place where you 3 could direct me to figure out what would be the 4 appropriate tests to identify the differences 5 between the explants and the controls?</p> <p>6 MR. ANDERSON: Objection as to form. 7 Go ahead.</p> <p>8 A. There's probably chapters like that, 9 books on chemical analysis that would suggest 10 methodologies.</p> <p>11 Generally you have a body of 12 experience developed over many years, you 13 just -- at this point in my life, I would know 14 that I need to look up additives, for example, 15 but then I would go to the Dr. Müller text which 16 is in our reference list to look up how 17 additives were used in various materials, and I 18 would look under polypropylene, and I would find 19 what additives are typically used for 20 polypropylene specifically. So I'd know what to 21 look for.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. And you're referring to a text cited 24 in your report by a Dr. Müller?</p> <p>25 A. Dr. Müller, Society of Plastics</p>	<p>1 development that are available today that 2 weren't available prior times. But, again, 3 today it's just -- every paper you read they 4 use -- we use some of the same methods. LCMS is 5 one of the bright and shining stars today that's 6 come -- really come on strong in the last 7 20 years, 10 to 20 years.</p> <p>8 Q. Real simple question, hopefully it's a 9 simple answer.</p> <p>10 Can you direct me to any authority, 11 textbook, article, whatever you use in your 12 business and in your expertise, that would 13 identify the tests that you would do to detect 14 the differences between an explanted piece of 15 polypropylene mesh and a pristine control of the 16 mesh?</p> <p>17 MR. ANDERSON: Objection. Asked and 18 answered.</p> <p>19 Go ahead.</p> <p>20 A. I don't know of any such text that 21 just has a single page where it lists -- if I 22 want to know about thermal methods, I'd go to 23 Edith Turi that I've cited. If I want to know 24 about GPC, I'd go to Modern GPC chromatography 25 text that I have. I have all these individual.</p>

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<p>1 And if you go to -- Odiam, for 2 example, would be another one that's a common 3 text that's used in polymer chemistry training 4 sessions at like University of Connecticut where 5 my son got his doctorate, he took -- he used 6 that text. In that text you will see a chapter 7 on DSC, you will see a chapter on GPC, you'll 8 see a chapter on IR, you'll see all these 9 various techniques.</p> <p>10 But it might not include every one I 11 used. I don't know that I can say -- I don't 12 think I can say there's any one book that has 13 every single method in it necessarily.</p> <p>14 Q. Is it fair to understand, Doctor, that 15 each of these tests that you ran were designed 16 to detect any differences between the control 17 sample of the mesh and the explant sample of the 18 mesh?</p> <p>19 A. That was the entire intent of the 20 proceeding, as far as I understood it. It was 21 just to look for differences, if there were any.</p> <p>22 Q. Okay. What is degradation?</p> <p>23 A. Well, degradation would be the loss of 24 functionalness of, in this case, a polymer for 25 its intended purpose.</p>	<p>1 that you analyzed?</p> <p>2 A. Well, SEM would be certainly a major 3 methodology. It gives you a visual observation 4 of -- I'd have to add SEM to the term 5 degradation, but it's a visual measurement as 6 opposed to a chemical measurement.</p> <p>7 Q. Okay.</p> <p>8 A. But it makes it very obvious if 9 something is degrading or not.</p> <p>10 Q. Other than degradation as you have 11 just defined it, and the SEM visual observations 12 that you've just described, did you look for any 13 other differences between the polypropylene in 14 the control samples and the polypropylene in the 15 explanted mesh?</p> <p>16 A. I'm not sure I understand how to 17 answer that question. We looked for differences 18 which included all the tests that we've 19 discussed; the molecular weight analysis, the 20 additives.</p> <p>21 Q. Don't all -- my question is; all the 22 tests that you ran are designed to determine the 23 extent to which the polypropylene degraded, is 24 that fair?</p> <p>25 A. Or could degrade. For example, if</p>
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<p>1 Q. Okay.</p> <p>2 A. That could include things like 3 oxidation, or environmental stress cracking. It 4 could include mechanical degradation. For 5 example, when products are -- waste materials in 6 the manufacturing process are re-used, they make 7 pellets out of the re-used material and they 8 call it regrind, and each regrind cycle tends to 9 degrade the polymer, so that's a type of 10 degradation.</p> <p>11 Q. Other than degradation as you've just 12 defined it, did you look for any other 13 differences in the polymer in the control sample 14 as compared to the polymer in the explant?</p> <p>15 A. Can I have the question repeated, 16 please?</p> <p>17 Q. Sure.</p> <p>18 Other than the degradation as you've 19 just defined it, did you look for any 20 differences -- I'm going to change the question 21 because I'm going to use a different term.</p> <p>22 Other than degradation as you've just 23 defined it, did you look for any differences in 24 the polypropylene in the control sample as 25 compared to the polypropylene in the explant</p>	<p>1 additives, antioxidants come out of the 2 polypropylene, initially it may not be degraded, 3 so I can't say that's degradation in and of 4 itself.</p> <p>5 However, once the antioxidants are out 6 of the polypropylene, it is now vulnerable to 7 oxidation. So it's a very valid technique in 8 predicting the longevity, the functionalness of 9 the product.</p> <p>10 Q. Okay. So can we define it this way; 11 that the tests that you ran, as you've just 12 identified them, were designed to determine the 13 extent to which the polypropylene in the 14 explanted mesh had degraded as compared to the 15 control, and the extent to which it might 16 degrade in the future?</p> <p>17 A. I like that better.</p> <p>18 Yes.</p> <p>19 Q. Okay. And you named three kinds, you 20 named oxidation, environmental stress cracking, 21 and mechanical degradation, is that fair?</p> <p>22 A. That's correct.</p> <p>23 Q. Your paper, your report discusses a 24 bunch of other types of degradation. Can we 25 focus on these three as being those types of</p>

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<p>1 degradation at which you looked for purposes of</p> <p>2 both Lewis and Batiste?</p> <p>3 A. Well, right. You would have -- you</p> <p>4 could have UV light degradation, but that</p> <p>5 wouldn't be applicable to this case.</p> <p>6 Q. The answer to my question, can we</p> <p>7 limit our questions in this case to oxidation,</p> <p>8 environmental stress cracking, mechanical</p> <p>9 degradation, and the SEM visual analysis of</p> <p>10 these meshes?</p> <p>11 MR. ANDERSON: Objection.</p> <p>12 Go ahead.</p> <p>13 A. Well, I want to be able to include</p> <p>14 FTIR, for example.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. But FTIR is designed to discuss --</p> <p>17 A. Show oxidation.</p> <p>18 Q. Right.</p> <p>19 A. I think we're in pretty good shape</p> <p>20 there.</p> <p>21 Q. Okay. All I'm trying to do is make</p> <p>22 this shorter instead of longer. And so I'm not</p> <p>23 trying to trick you at all, believe it or not.</p> <p>24 All right. So you received -- first</p> <p>25 of all, who hired you in this case?</p>	<p>1 the --</p> <p>2 (Witness reviewing documents.)</p> <p>3 A. So the control samples were received</p> <p>4 for analysis in sealed packaging.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. My question is pretty simple, I think.</p> <p>7 Maybe it's not. Page 12, you talk about sample</p> <p>8 preparation.</p> <p>9 A. Right.</p> <p>10 Q. Where did you go to determine how to</p> <p>11 prepare your sample for preparation for your</p> <p>12 analysis? Did you consult any text, or are</p> <p>13 there standard methodologies that you use to</p> <p>14 prepare your samples for the testing that you're</p> <p>15 going to do?</p> <p>16 A. Well, in the case with polymers like</p> <p>17 this, we have a balance area, we have a standard</p> <p>18 area with an optical microscope, and we have</p> <p>19 scalpels, and we have tweezers, and disposable</p> <p>20 scalpels, and aseptic tweezers, that's just our</p> <p>21 SOP.</p> <p>22 And so we would cut the samples, cut</p> <p>23 off little pieces for various -- because</p> <p>24 different methods require different amounts of</p> <p>25 sample.</p>
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<p>1 A. Mr. Anderson.</p> <p>2 Q. And you've already described what</p> <p>3 Mr. Anderson asked you to do. And you</p> <p>4 determined on your own what battery of tests to</p> <p>5 conduct in order to evaluate the control mesh</p> <p>6 against the explanted mesh, correct?</p> <p>7 A. That's correct.</p> <p>8 Q. When you received the samples that you</p> <p>9 were to compare, I'm talking about the control</p> <p>10 samples and the mesh explant samples, how did</p> <p>11 you determine how to prepare those samples for</p> <p>12 testing?</p> <p>13 MR. ANDERSON: Objection.</p> <p>14 Do you want to talk about the control</p> <p>15 or the mesh?</p> <p>16 MR. THOMAS: Both.</p> <p>17 MR. ANDERSON: Okay.</p> <p>18 MR. THOMAS: I'll do it first.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. How did you determine how to prepare</p> <p>21 your control samples for testing?</p> <p>22 A. Well, with the control samples we had</p> <p>23 more material, boxes came in, and we had</p> <p>24 pictures in here of the process. I think that</p> <p>25 may be the best place to do, is just go look at</p>	<p>1 Q. Did you rely on your own internal</p> <p>2 standard operating procedures for your sample</p> <p>3 preparations for the tests that you conducted?</p> <p>4 A. Yes.</p> <p>5 Q. Are the standard operating procedures</p> <p>6 that you have for Jordi Labs to conduct this</p> <p>7 analysis in writing?</p> <p>8 A. Most of them are, yes. As far as -- I</p> <p>9 don't know if we have an SOP, I have to check on</p> <p>10 that, for actual cutting of the samples.</p> <p>11 MR. ANDERSON: He just said</p> <p>12 "preparation." So I'm not sure --</p> <p>13 THE WITNESS: That is preparation,</p> <p>14 yes.</p> <p>15 MR. ANDERSON: Fair enough.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. And how would you describe the</p> <p>18 standard operating procedures for Jordi Labs, if</p> <p>19 I wanted to identify them to get them at a later</p> <p>20 time, that you did for sample preparation?</p> <p>21 A. I don't know if we have a written for</p> <p>22 sample preparation as far as just cutting the</p> <p>23 samples. We have SOPs like for GPC, how to</p> <p>24 dissolve the samples, FTIR, how it's put on the</p> <p>25 instrument for each of those techniques, once</p>

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<p>1 the samples are passed to each specific analyst.  2 But as far as -- I have a whole pile of SOPs  3 over here for you for each of those methods.  4 Q. Okay. Probably what I'll do during  5 lunch.  6 MR. ANDERSON: That's why the question  7 is a little tough. When you're saying sample  8 preparation, there's all these different tests  9 that were done, so the question embodies a lot  10 of things. I didn't want to keep objecting.  11 MR. THOMAS: I appreciate that.  12 BY MR. THOMAS:  13 Q. On Page 12 of your report, under  14 "Sample Preparation," you discuss a "Control  15 Experiment." It says "The control samples were  16 also used as part of a control experiment  17 designed to provide an indication as to the  18 effects of formalin storage."  19 Why did you conduct a control  20 experiment designed to provide indication as to  21 the effects of formalin storage?  22 A. The samples received from Steelgate  23 came informally, they were shipped to us that  24 way, and we wanted to know what effect formalin  25 would have on pristine polypropylene, or not, as</p>	<p>1 Q. Continuing on Page 12, you discuss  2 taking a sample of each control material, about  3 100 milligrams, placing it in formalin,  4 90 milliliters and heat it at 60 degrees  5 centigrade for 48 hours. "In my experience,  6 this temperature would be expected to provide an  7 accelerated rate of aging and is consistent with  8 other published methods for this purpose."  9 What does that mean?  10 A. Well, the samples have been sitting in  11 storage at Steelgate for some time, we don't  12 know how long exactly, at least I don't. The --  13 so if it had been in Steelgate for a month, and  14 we put it in formalin here for a day, it  15 wouldn't be equivalent treatment. So to get it  16 as close to being equivalent treatment as we  17 could we tried to -- in effect, we tried to  18 accelerate any potential aging by running it at  19 -- like doing the storage at 60 for 48 hours, so  20 it would be more like the treatment that it  21 would have received for, say, a month, or  22 whatever the time was, from Steelgate.  23 Q. You cite to two references for this  24 process, it's the ASTM Standard D3045, and the  25 Inoue paper, 1961, the Journal of Polymer</p>
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<p>1 the case might be, so we wanted to rule out any  2 potential oxidation caused by formalin of the  3 explants that were slipped to us, so we tried  4 the controls the same way.  5 Q. What is it about formalin that caused  6 you to be concerned about potential oxidation to  7 the mesh?  8 A. Nothing specifically. It's just good  9 lab practice to make sure that you treat -- if I  10 want to compare a pristine mesh with an explant,  11 I want the pristine mesh that I'm calling a  12 standard to be treated identically, period, as  13 much as I possibly can control it, to the  14 explant material. Since the explant was in  15 formalin, it's wise to put your control in  16 formalin so they're treated identically. So any  17 differences then seen can't be attributed to the  18 formalin treatment, if there was any. I didn't  19 know there was or not. But that is just good  20 lab practice to me.  21 Q. As a biochemist, are you aware of any  22 chemical reaction issues associated between  23 formalin and polypropylene that may affect the  24 chemical properties of polypropylene?  25 A. In general, no.</p>	<p>1 Science on Page 13 of your report.  2 A. Correct.  3 Q. Do those two references support using  4 60 degrees centigrade for 48 hours to replicate  5 the aging process of polymer controls?  6 A. Well, various methods are used. But  7 in general the principle -- definitely supports  8 the principle. Various temperatures and times  9 are given for various polymers, and so this was  10 just trying to follow the principles.  11 Q. What age of explants in formalin does  12 60 degrees centigrade for 48 hours for the  13 controls represent?  14 A. As to age at room temperature,  15 specifically I don't know.  16 Q. Okay. Why did you choose 60 degrees  17 centigrade for 48 hours?  18 A. Because that was consistent with these  19 two references that would be recommended. If it  20 doesn't show -- the point being if it doesn't  21 show up in this temperature in this amount of  22 time, it likely isn't going to react.  23 Q. Okay. So is it fair to understand  24 that the 60 degrees centigrade for 48 hours is  25 not designed to reflect any specific time that</p>

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<p>1 the explants may have been in formalin, but</p> <p>2 designed to determine if the formalin would have</p> <p>3 any degradation on the controls at any time?</p> <p>4 A. It was determined -- it was an attempt</p> <p>5 to determine if formalin would react with</p> <p>6 polypropylene.</p> <p>7 Q. And what did your experiment conclude?</p> <p>8 A. All the tests, SEM, and all the rest</p> <p>9 of the tests, FTIR, showed no change.</p> <p>10 Q. So is it your conclusion from that</p> <p>11 analysis that formalin has no chemical impact on</p> <p>12 polypropylene?</p> <p>13 A. That's correct.</p> <p>14 Q. Have you done any research to</p> <p>15 determine the extent to which formalin has any</p> <p>16 impact on polypropylene?</p> <p>17 A. No, I have not.</p> <p>18 Q. Formalin is --</p> <p>19 A. Other than the test.</p> <p>20 MR. ANDERSON: What did you say?</p> <p>21 A. Other than this test, of course.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Formalin is a mixture of formaldehyde?</p> <p>24 A. Yes.</p> <p>25 Q. Did you do any research to determine</p>	<p>1 to preserve their explant samples?</p> <p>2 A. Because it's a preservative.</p> <p>3 Q. When you say "preservative," does that</p> <p>4 have a chemical meaning to you?</p> <p>5 A. It has a more of a biological meaning.</p> <p>6 The formaldehyde preserves tissue and preserves</p> <p>7 anything from anything that's in it, from</p> <p>8 bacterial growth which would degrade biological</p> <p>9 materials.</p> <p>10 Q. Okay. You said two things there, as I</p> <p>11 heard it. I'm going to do the second one first.</p> <p>12 You said it prevents bacterial growth.</p> <p>13 Tell me what that means, please.</p> <p>14 A. Well, in tissue, if you have -- by</p> <p>15 itself it just will pick up bacteria from flies</p> <p>16 landing on it or just from the air, and then it</p> <p>17 will begin to degrade.</p> <p>18 Q. Okay. So it would be the influence of</p> <p>19 the outside bacteria growing on the explant that</p> <p>20 may have an impact on the chemical composition</p> <p>21 of the explant, is that fair?</p> <p>22 A. That's one piece of it. But another</p> <p>23 piece would be if there were bacteria in the</p> <p>24 tissue -- for example, if there were an</p> <p>25 infection in the mesh that was taken out, that</p>
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<p>1 the extent to which formaldehyde had any</p> <p>2 chemical impact on polypropylene?</p> <p>3 A. Well, in all the published literature,</p> <p>4 I looked at all these articles, I read over 400</p> <p>5 pages, various authors determined -- did various</p> <p>6 studies of explanted materials. Everybody in</p> <p>7 the world, as far as I can see, treats their</p> <p>8 samples with -- or essentially everyone uses</p> <p>9 formaldehyde as a preservative. If you didn't</p> <p>10 do that, you would allow for potential bacterial</p> <p>11 growth and things like that that might degrade</p> <p>12 the polymer.</p> <p>13 Q. My question was different.</p> <p>14 Dr. Jordi, did you do any research to</p> <p>15 determine the extent to which formaldehyde can</p> <p>16 have a chemical reaction with and degrade</p> <p>17 polypropylene?</p> <p>18 A. No.</p> <p>19 MR. ANDERSON: Objection.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. A minute ago you said that everyone</p> <p>22 uses formaldehyde to preserve their -- what?</p> <p>23 A. Their explant samples.</p> <p>24 Q. Okay. And do you have an</p> <p>25 understanding of why everyone uses formaldehyde</p>	<p>1 would be bacteria, it could continue to grow as</p> <p>2 well. I can't sort that out.</p> <p>3 Q. Okay. The other thing you said, as I</p> <p>4 wrote it down, is that formaldehyde preserves</p> <p>5 tissue.</p> <p>6 How does formaldehyde preserve tissue?</p> <p>7 A. It makes for an aseptic environment.</p> <p>8 Bacteria can't grow in it, so hence, there's no</p> <p>9 degradation.</p> <p>10 Q. So it's actually consistent with your</p> <p>11 second point, and that is it arrests the</p> <p>12 development of bacteria to prevent any</p> <p>13 degradation of the explant, is that correct?</p> <p>14 A. That's the intent, yes.</p> <p>15 Q. Are you aware of any chemical reaction</p> <p>16 that formaldehyde has with proteins that may be</p> <p>17 on explants?</p> <p>18 A. Absolutely. Formaldehyde is an</p> <p>19 aldehyde, and it will react with any things like</p> <p>20 amines. It can react with any other reactor</p> <p>21 group that typical aldehydes with react with.</p> <p>22 Q. As a part of your analysis in this</p> <p>23 case, did you study the impact of formaldehydes</p> <p>24 on any proteins that may be on explanted meshes?</p> <p>25 A. No, we did not.</p>

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<p>1 Q. Did you consider that issue at all in</p> <p>2 your analysis?</p> <p>3 A. No.</p> <p>4 Q. Doctor, you identified three types of</p> <p>5 degradation which you analyzed in connection</p> <p>6 with your work in Exhibits 1 and 2, and one was</p> <p>7 oxidation, the second was environmental stress</p> <p>8 cracking, and the third was mechanical</p> <p>9 degradation, correct?</p> <p>10 A. Yes.</p> <p>11 Q. What evidence in your testing for</p> <p>12 Exhibit 1 for the Lewis case did you find</p> <p>13 oxidation?</p> <p>14 A. For that we're going to have to go to</p> <p>15 the report.</p> <p>16 MR. ANDERSON: Anything you need to</p> <p>17 reference in your report you can reference it.</p> <p>18 A. Well, the first thing we saw -- that</p> <p>19 we looked at was SEM, and then that's coupled</p> <p>20 with SEM-EDX, so we'll look at a couple SEM</p> <p>21 charts first.</p> <p>22 Page 26 shows a typical explanted</p> <p>23 sample. Figure 16 shows transverse cracks of</p> <p>24 surface polypropylene.</p> <p>25 BY MR. THOMAS:</p>	<p>1 I'll explore each of those in a little more</p> <p>2 detail rather than going through the report and</p> <p>3 finding each one.</p> <p>4 Does that make sense?</p> <p>5 MR. ANDERSON: Your question was all</p> <p>6 the evidence of oxidation, so that made it a</p> <p>7 little tougher.</p> <p>8 MR. THOMAS: I'm sorry. I'm not very</p> <p>9 smart sometimes.</p> <p>10 MR. ANDERSON: It's not about smart.</p> <p>11 I think he wants a more general</p> <p>12 question to begin with, and then he'll go into</p> <p>13 the --</p> <p>14 A. Well, SEM-EDX, for sample, showed --</p> <p>15 SEM-EDX showed increased oxygen levels in the</p> <p>16 cracked region that we just talked about.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Okay.</p> <p>19 A. And you don't want to talk about</p> <p>20 figures at this point?</p> <p>21 Q. No.</p> <p>22 A. Just concepts?</p> <p>23 Q. Exactly. Thank you.</p> <p>24 A. All right. I'll try to do my best,</p> <p>25 sir.</p>
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<p>1 Q. Let me stop you there, if I can. Are</p> <p>2 you finished?</p> <p>3 A. Yes.</p> <p>4 Q. I don't want to interrupt you.</p> <p>5 The surface cracking that you just</p> <p>6 described on the record, this is your visual</p> <p>7 observation that you talked about before that</p> <p>8 you believe is evidence of oxidation, is that</p> <p>9 correct?</p> <p>10 A. This is visual evidence of either</p> <p>11 oxidation or environmental stress cracking, or</p> <p>12 both, and by itself it can't tell you the</p> <p>13 difference.</p> <p>14 Q. Got you.</p> <p>15 But it's strictly visual?</p> <p>16 A. This one is visual, yes, sir.</p> <p>17 Figure 22 is another good example.</p> <p>18 Q. What page are we on, please?</p> <p>19 A. 29. Flaking polypropylene pieces.</p> <p>20 Q. Now, you can do whatever you want to,</p> <p>21 I'm looking for -- perhaps it would be easier</p> <p>22 this way. You don't have to do all the figures</p> <p>23 that talk about visual observations. What I'm</p> <p>24 looking for specifically is each type of</p> <p>25 oxidation that you found in your report, then</p>	<p>1 Q. You're doing fine.</p> <p>2 A. DSC showed a decrease in the heat</p> <p>3 effusion, and a decrease in the melt temperature</p> <p>4 versus non-cracked material. That correlates</p> <p>5 with environmental stress cracking, because the</p> <p>6 Delta H at melt correlates with the amount or</p> <p>7 the percentage of crystallinity, and hence the</p> <p>8 percentage of amorphous materials, which allows</p> <p>9 things like cholesterol and cholesterol esters</p> <p>10 and fatty acids to get into the cracking.</p> <p>11 FTIR microscopy clearly showed -- by</p> <p>12 using the microscopic version of FTIR, coupled,</p> <p>13 we were able to actually take IRs of each flaked</p> <p>14 piece, and this flaked piece clearly showed</p> <p>15 protein and polypropylene. And since the</p> <p>16 polypropylene bands are weaker than carbonyl</p> <p>17 bands, they're alkyl, absorbance bands versus</p> <p>18 carbonyl, this chart that I'm looking at of this</p> <p>19 particular flaked piece would be estimated to be</p> <p>20 about 75 percent or so polypropylene, maybe</p> <p>21 25 percent protein.</p> <p>22 Q. Okay.</p> <p>23 A. Because they're both there.</p> <p>24 Q. And just generally for now, we'll go</p> <p>25 specifically to those issues later.</p>

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<p>1 A. Okay. The molecular weight averages</p> <p>2 that were determined showed basically no</p> <p>3 difference between cracked samples and pristine.</p> <p>4 Q. Help me there.</p> <p>5 A. And formalin treated.</p> <p>6 Q. That is not evidence of oxidation, is</p> <p>7 it, the fact that they're the same?</p> <p>8 A. Are you asking only for evidence of</p> <p>9 oxidation?</p> <p>10 Q. Correct.</p> <p>11 A. Okay. We'll skip that.</p> <p>12 Q. Just so we're clear --</p> <p>13 A. Right.</p> <p>14 Q. -- the molecular weight analysis you</p> <p>15 did is not consistent with oxidation?</p> <p>16 A. In and of, and by itself it is not.</p> <p>17 Q. Thank you.</p> <p>18 A. PYMS showed generally a lack of -- or</p> <p>19 very great minimization of both Santonox R and</p> <p>20 lauryl thiodipropionate.</p> <p>21 Q. Okay. And those are antioxidants?</p> <p>22 A. Those are the two antioxidants that</p> <p>23 are in the formulation, in the recipe from</p> <p>24 Ethicon.</p> <p>25 Q. Is it fair to understand, though, that</p>	<p>1 BY MR. THOMAS:</p> <p>2 Q. Yes.</p> <p>3 A. Generally the percentage of oxygen in</p> <p>4 oxidized polypropylene, at least initially, is</p> <p>5 in the low percent range. So it doesn't take</p> <p>6 very much increase in oxygen in polypropylene to</p> <p>7 cause embrittlement, rigidity, and those kind of</p> <p>8 effects. Those are caused by presence of</p> <p>9 ketones and aldehydes as the oxidation goes on,</p> <p>10 carboxylic acids if it goes far enough.</p> <p>11 Q. Doctor, my question is a little more</p> <p>12 specific than that.</p> <p>13 Did you attempt to measure the extent</p> <p>14 of oxidation in any of the mesh implants</p> <p>15 quantitatively?</p> <p>16 A. It would be relative quantitation,</p> <p>17 comparing control versus explant.</p> <p>18 Q. Did you express any measurement of</p> <p>19 oxidation in the explants compared to the</p> <p>20 controls in your report?</p> <p>21 A. I'm sorry, can you repeat the</p> <p>22 question?</p> <p>23 Q. Did you set forth any opinion as to</p> <p>24 the extent of oxidation from the explants</p> <p>25 measured quantitatively in your report?</p>
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<p>1 the PYMS analysis does not show oxidation, but</p> <p>2 is part of your earlier analysis about potential</p> <p>3 future oxidation?</p> <p>4 A. That's correct, it is. Okay.</p> <p>5 Q. So the PYMS analysis itself does not</p> <p>6 show oxidation of the polypropylene in the</p> <p>7 explants?</p> <p>8 A. It shows vulnerability to oxidation is</p> <p>9 what it shows.</p> <p>10 Q. It does not show any oxidation in the</p> <p>11 explants?</p> <p>12 A. In and of itself, no.</p> <p>13 Q. Thank you.</p> <p>14 Have we covered the basics on the</p> <p>15 oxidation?</p> <p>16 A. I think so.</p> <p>17 Q. For those places where you found</p> <p>18 evidence of oxidation, as you've just described</p> <p>19 and as reflected in your report, were you ever</p> <p>20 able to measure the extent of antioxidation of</p> <p>21 the explants that you analyzed?</p> <p>22 MR. ANDERSON: Objection.</p> <p>23 Go ahead.</p> <p>24 A. Are you talking about quantitative</p> <p>25 numbers now?</p>	<p>1 MR. ANDERSON: Objection.</p> <p>2 Go ahead.</p> <p>3 A. Again, it was a relative thing, so I</p> <p>4 don't know that I can say. It would be</p> <p>5 quantitative.</p> <p>6 But, for example, pristine</p> <p>7 polypropylene didn't show any carbonyl to 1760,</p> <p>8 1740 that we could see. But the explants did.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. Did you attempt to measure in that</p> <p>11 context the extent to which the carbonyl issue</p> <p>12 had any impact on the ability of the</p> <p>13 polypropylene to function for its intended</p> <p>14 purpose?</p> <p>15 A. All oxidation is bad. It's a relative</p> <p>16 determination. So you would hope there wouldn't</p> <p>17 be any carbonyl observed, is what you would look</p> <p>18 for if the material is good.</p> <p>19 Your question, I'm sorry.</p> <p>20 Q. Might have been a bad question. Let</p> <p>21 me see if I can do it again.</p> <p>22 In your analysis of oxidation, did you</p> <p>23 ever measure the extent to which the</p> <p>24 polypropylene in the explanted meshes was</p> <p>25 degraded in a quantitative way?</p>

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<p>1 A. In a relative quantitative way is all</p> <p>2 we did.</p> <p>3 Q. And tell me what that means.</p> <p>4 A. Well, that means if I have a peak for</p> <p>5 carbonyl, I have -- like if I had no peak in the</p> <p>6 pristine and I have a peak, a measurable peak in</p> <p>7 the explant, then I can say with certainty that</p> <p>8 the explanted material is more oxidized than the</p> <p>9 pristine.</p> <p>10 Q. Are we talking about oxidation to the</p> <p>11 extent that it compromises the ability of the</p> <p>12 polymer to function for its intended purpose?</p> <p>13 A. The only way I know to answer this is</p> <p>14 in science we would pool multiple methods. I</p> <p>15 have to look at the SEM photographs and look at</p> <p>16 the carbonyl levels and try to correlate the</p> <p>17 carbonyl with the degree of damage actually</p> <p>18 observed physically in the SEM. So that's the</p> <p>19 kind of thing what I mean by "relative."</p> <p>20 Q. Do you have an opinion as you sit here</p> <p>21 today, based on your training, education,</p> <p>22 experience, and review of the materials in this</p> <p>23 case, of the extent to which the polypropylene</p> <p>24 in the mesh explants oxidized in the context of</p> <p>25 the loss of functionalness for its intended</p>	<p>1 they were handed to the appropriate technician</p> <p>2 to do the sampling that's described in the</p> <p>3 photograph. They're removed -- now you're</p> <p>4 talking about the actual --</p> <p>5 Q. Explants, correct.</p> <p>6 A. -- explant.</p> <p>7 Received tissue bundles.</p> <p>8 Q. You're on page?</p> <p>9 A. Now I'm on 16.</p> <p>10 Q. Thank you.</p> <p>11 A. And little pieces were cut off with</p> <p>12 disposable scalpel. And the picture on the</p> <p>13 right -- I'll wait for you to get there if you</p> <p>14 want.</p> <p>15 Q. I'm fine. Go ahead.</p> <p>16 A. Little pieces were cut off, and that's</p> <p>17 what was then repackaged in formalin for</p> <p>18 shipment for SEM.</p> <p>19 Q. Okay. As we look on Page 16, there</p> <p>20 are four photos there in Figure 2. The top left</p> <p>21 photo in Figure 2 is the way that you received</p> <p>22 the sample?</p> <p>23 A. Yes.</p> <p>24 Q. Dumped out of container, is that fair?</p> <p>25 MR. ANDERSON: Objection.</p>
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<p>1 purpose?</p> <p>2 A. Yes, I do.</p> <p>3 Q. Okay. What is that opinion?</p> <p>4 A. The material appears degraded, some of</p> <p>5 it severely degraded. There's a range from</p> <p>6 sample to sample. And in two cases of 23</p> <p>7 samples that we ran, we didn't see any damage.</p> <p>8 91 percent of the time we did.</p> <p>9 Q. Are you talking now about your visual</p> <p>10 observations through the scanning electron</p> <p>11 microscopy?</p> <p>12 A. Yes, correlating that, of course, with</p> <p>13 the carbonyls.</p> <p>14 Q. I'm talking about the analysis that we</p> <p>15 -- strike that. Let me come back to that.</p> <p>16 Doctor, let's go back to your sample</p> <p>17 preparation. That's what happens when I find</p> <p>18 rabbit holes.</p> <p>19 What steps did you take to prepare the</p> <p>20 explants that you received for analysis?</p> <p>21 MR. ANDERSON: Objection.</p> <p>22 Go ahead.</p> <p>23 A. Well, the samples were received at our</p> <p>24 receiving area, and then they were -- the boxes</p> <p>25 were photographed, and they were removed, and</p>	<p>1 A. Yes.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. I'm sorry, I'm trying to be casual.</p> <p>4 Excuse me. That was a bad question.</p> <p>5 Mr. Anderson is exactly right.</p> <p>6 Dr. Jordi, is it fair to understand</p> <p>7 that the top left on Figure 16 reflects the</p> <p>8 samples as received before you did anything to</p> <p>9 them?</p> <p>10 A. That's correct.</p> <p>11 Q. And how did you separate the mesh in</p> <p>12 the lower left-hand corner in Figure 2 from the</p> <p>13 tissue that appears on the lower right-hand</p> <p>14 corner of Figure 2?</p> <p>15 A. We utilized forceps to pull the tissue</p> <p>16 off of the sample. As you can see, in the left</p> <p>17 bottom picture there are little bits of tissue</p> <p>18 left.</p> <p>19 Q. Who did that? Did you do that?</p> <p>20 A. Adi Kulcarni. Took about an hour a</p> <p>21 sample.</p> <p>22 Q. And did you use forceps in each hand,</p> <p>23 is that how you do that? Or how do you do that?</p> <p>24 A. He just -- he has to hold it, he has</p> <p>25 to hold it while he pulls tissue off.</p>

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<p>1 Q. Hold it in his hand?</p> <p>2 A. No. With forceps.</p> <p>3 Q. So you've got the forceps?</p> <p>4 A. Two, yes.</p> <p>5 Q. Two forceps.</p> <p>6 Is there a Jordi standard operating</p> <p>7 procedure about how to remove tissue from mesh?</p> <p>8 A. No.</p> <p>9 Q. How was it determined how to remove</p> <p>10 the tissue from the mesh?</p> <p>11 A. Well, the technique was to remove the</p> <p>12 tissue touching the -- as little as possible the</p> <p>13 mesh itself so that you wouldn't cause any</p> <p>14 damage to it.</p> <p>15 Q. Did you instruct this technician -- is</p> <p>16 that the right word?</p> <p>17 A. No. He's a Ph.D.</p> <p>18 Q. Did you instruct -- what's his name</p> <p>19 again? I'm sorry.</p> <p>20 A. Adi Kulcarni.</p> <p>21 Q. Did you instruct Dr. Kulcarni on the</p> <p>22 method to separate the mesh from this tissue?</p> <p>23 A. No, I did not.</p> <p>24 Q. Do you know what procedure he followed</p> <p>25 or what -- strike that.</p>	<p>1 Dr. Kulcarni about the methodology to separate</p> <p>2 the tissue from the mesh?</p> <p>3 A. No. It appeared very gentle, as good</p> <p>4 as we could possibly do.</p> <p>5 Q. Okay. Other than separating the</p> <p>6 tissue from the mesh, as you've just described</p> <p>7 in Figure 2 on Page 16 of your report, which is</p> <p>8 Exhibit Number 1, were there any efforts made to</p> <p>9 otherwise treat the mesh prior to testing?</p> <p>10 A. No.</p> <p>11 Q. For the tissue sample that appears in</p> <p>12 the upper left of Figure 2 on Page 16, was there</p> <p>13 any discussion about trying to clean that</p> <p>14 sample?</p> <p>15 A. Well, that's what we've just been</p> <p>16 discussing. This was how it was cleaned, it was</p> <p>17 done with forceps.</p> <p>18 Q. Okay. At any time was there a</p> <p>19 discussion with Dr. Kulcarni about cleaning the</p> <p>20 mesh that was removed from the tissue to remove</p> <p>21 proteinaceous material from the mesh?</p> <p>22 A. No.</p> <p>23 Q. Is it fair to understand, Dr. Jordi,</p> <p>24 that the mesh that appears on Page 16 in the</p> <p>25 lower left-hand corner is mesh that has been</p>
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<p>1 Do you know what methodology he</p> <p>2 followed in order to protect the integrity of</p> <p>3 the mesh and the tissue as he separated the two?</p> <p>4 A. Well, it was set out, I believe, on a</p> <p>5 piece of tissue so it wouldn't be contaminated</p> <p>6 with anything in the area. It was a clean work</p> <p>7 area to begin with, and used aseptic forceps.</p> <p>8 Q. Is there a standard methodology, of</p> <p>9 which you're aware, that tells Dr. Kulcarni how</p> <p>10 to properly separate the mesh from the tissue?</p> <p>11 A. I don't think so. I don't think one</p> <p>12 exists. I've never seen one.</p> <p>13 Q. Did you discuss with Dr. Kulcarni how</p> <p>14 to appropriately separate the mesh and tissue?</p> <p>15 A. Did I discuss with him how to do it?</p> <p>16 Q. Yes.</p> <p>17 A. We discussed -- yes, we had</p> <p>18 discussions. But, you know, he is a very, very</p> <p>19 careful worker.</p> <p>20 Q. What was the purpose of your</p> <p>21 discussions with Dr. Kulcarni about how to</p> <p>22 separate the tissue from the mesh?</p> <p>23 A. I wanted to see the samples for</p> <p>24 myself. That's all.</p> <p>25 Q. Did you have any discussions with</p>	<p>1 separated from the tissue without further</p> <p>2 cleaning?</p> <p>3 A. That's correct.</p> <p>4 Q. Did you ever consider cleaning the</p> <p>5 mesh that was separated from the tissue in order</p> <p>6 to -- strike that.</p> <p>7 Did you ever consider cleaning the</p> <p>8 mesh that was separated from the tissue prior to</p> <p>9 conducting your tests that you did in Exhibit 1?</p> <p>10 A. At the time this work was done, no.</p> <p>11 Q. Before you did your work in Exhibits 1</p> <p>12 and 2, did you do any research into analysis by</p> <p>13 other scientists in the methodology for testing</p> <p>14 explanted meshes?</p> <p>15 A. I did.</p> <p>16 Q. And what research did you do?</p> <p>17 A. I read a number of articles, Clavé and</p> <p>18 others.</p> <p>19 Q. You read Costello?</p> <p>20 A. Costello.</p> <p>21 Q. Did you read de Tayrac?</p> <p>22 A. Yes.</p> <p>23 Q. Before you did your testing in this</p> <p>24 case?</p> <p>25 A. No. It's recent.</p>

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<p>1 (Whereupon, Jordi Exhibit Number 3, 2 de Tayrac and Letouzey article titled 3 "Basic science and clinical aspects of 4 mesh infection in pelvic floor 5 reconstructive surgery, was marked for 6 identification.) 7 A. Are you going to de Tayrac? 8 BY MR. THOMAS: 9 Q. Yes. 10 Let me show you what I marked as 11 deposition Exhibit Number 3. You have Exhibit 12 Number 3 in the materials that you brought with 13 you today? 14 A. Yes, I do. I'm looking for it. Here 15 it is right here, de Tayrac. 16 Q. When did you obtain your copy of 17 Exhibit Number 3, which is an article published 18 in the -- by Renaud de Tayrac and Vincent 19 Letouzey, it appears in International 20 Urogynecology Journal in 2011? When did you 21 first receive that? 22 A. I don't recall exactly, because I 23 receive so many articles. I remember reading it 24 fairly recently, within the last two weeks. 25 Q. Did you have a chance to review</p>	<p>1 in the lower left-hand corner you have the mesh 2 separated from the tissue, correct? 3 A. Correct. 4 Q. And you understand when the mesh is in 5 the body -- was in the body it was surrounded by 6 materials in the body? 7 A. That's right. 8 Q. Including proteins? 9 A. And those materials are shown in the 10 bottom right picture. That is the material 11 removed. 12 Q. Okay. Is it your opinion that after 13 the mesh is separated from the tissue that 14 there's no longer any protein material on the 15 mesh? 16 A. No, I believe there still is some 17 protein on the mesh. We can see it, we can see 18 tissue, bits and pieces. 19 Q. All right. Are you familiar with the 20 term known as biofilm? 21 A. Yes. 22 Q. What do you understand a biofilm to 23 be? 24 A. Well, biofilm would be a covering 25 material that coats things in the body. As far</p>
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<p>1 Exhibit 3 prior to the time that you conducted 2 your work in Exhibits 1 and 2? 3 A. No. 4 Q. If you turn to Page 778 of Exhibit 3, 5 read as much as you need to. 6 A. 778? 7 Q. That's right. You're on the right 8 page. 9 A. This is 780 in mine. 10 MR. ANDERSON: Top right. 11 A. Got it. Top left. 12 MR. ANDERSON: Top left, yes. 13 A. All right. 14 MR. ANDERSON: After you finish 15 de Tayrac, can we take a break? 16 MR. THOMAS: Sure. Take a break right 17 now if you'd like to. 18 MR. ANDERSON: Sure. 19 MR. THOMAS: Let's do that. 20 (Whereupon, a recess was taken from 21 10:13 a.m. to 10:25 o'clock a.m.) 22 BY MR. THOMAS: 23 Q. Let's go back and make this more 24 clear. Go to Page 16 of your report. 25 On Page 16 of your report on Figure 2</p>	<p>1 as its chemical composition, I've never seen it 2 described in these papers that I've read any 3 more than to say biofilm. But obviously 4 protein, probably glycoproteins. 5 Q. Would you expect a biofilm to surround 6 the mesh that is in the explant samples that you 7 analyzed? 8 MR. ANDERSON: Objection. 9 Go ahead. 10 A. I think that's a very distinct 11 possibility that would be there. Whether it 12 would totally surround it or not, I would have 13 to look at a specific SEM. 14 BY MR. THOMAS: 15 Q. All right. Did you make any effort in 16 your sample preparation as reflected on Page 16 17 of Exhibit Number 1 to remove all protein 18 materials or biofilms from the mesh before 19 analysis? 20 A. No, we did not. We didn't want to 21 take tremendous efforts in -- effort is not the 22 right word. But we didn't want to do anything 23 that would try to disturb the mesh. 24 So for SEM, for example, looking at 25 the upper right picture, we cut a piece of</p>

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<p>1 tissue off, and the SEM was actually taken on</p> <p>2 the fibers imbedded in the tissue so that we</p> <p>3 didn't have to pull the fibers out. Because we</p> <p>4 were afraid that with forceps we might cause</p> <p>5 scarring of the surface, and we didn't want to</p> <p>6 cause anything like that if we could avoid it.</p> <p>7 So that was done to -- we didn't even remove the</p> <p>8 tissue in that case for the SEM work, because we</p> <p>9 didn't want to risk injuring the fibers.</p> <p>10 Now, we had to get the fibers clear to</p> <p>11 do DSC, FTIR, GPC, so that's why the tissue was</p> <p>12 removed for those studies.</p> <p>13 Q. You are aware that using forceps to</p> <p>14 separate the tissue from the mesh can impact the</p> <p>15 physical integrity of the mesh?</p> <p>16 MR. ANDERSON: Objection.</p> <p>17 Go ahead.</p> <p>18 A. We were very gentle in how we did</p> <p>19 this, and it's described in our procedure. We</p> <p>20 tried every way we possibly could to take great</p> <p>21 care to not disturb the mesh. So with forceps</p> <p>22 we could grab two pieces of tissue and not ever</p> <p>23 touch the mesh to pull it apart.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. Okay. But you made no further effort</p>	<p>1 Q. And de Tayrac finds that the</p> <p>2 degradation is due to the biofilm, correct?</p> <p>3 A. That's what the paper says.</p> <p>4 Q. Do you disagree with that?</p> <p>5 A. I do.</p> <p>6 Q. Why?</p> <p>7 A. It's best showing you in my picture.</p> <p>8 Can I show you a figure?</p> <p>9 Q. Okay.</p> <p>10 A. Go to the FTIR section of my report,</p> <p>11 I'll give you a page here in a minute, Page 71,</p> <p>12 for example. There's a number of pages. 71 is</p> <p>13 as good as any, I guess.</p> <p>14 There's protein here, and as evidenced</p> <p>15 by the 1653, the 1531, amide 1, and amide 2</p> <p>16 bands. But there's also polypropylene, 1445,</p> <p>17 1377, and then the four little atactic bands</p> <p>18 that are shown to the right of the 1377 band.</p> <p>19 And since the alkyl bands are less intense than</p> <p>20 the carbonyl bands of the protein, or any other</p> <p>21 carbonyl types, this would be about a 75 percent</p> <p>22 polypropylene, give or take a little, and maybe</p> <p>23 25 percent protein, or what you would call</p> <p>24 biofilm.</p> <p>25 So this is the stuff that they</p>
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<p>1 to clean the mesh to remove any protein or</p> <p>2 biofilm that remained after removing the mesh</p> <p>3 with the forceps, correct?</p> <p>4 A. Correct.</p> <p>5 Q. Now, you've now read de Tayrac, and</p> <p>6 de Tayrac analyzes the results that Clavé found</p> <p>7 in his study, correct?</p> <p>8 A. That's correct.</p> <p>9 Q. And they state on Page 778, "We also</p> <p>10 experimentally tested Clavé's conclusion</p> <p>11 regarding a correlation between infection and</p> <p>12 polypropylene 'degradation'."</p> <p>13 A. Where are you, sir?</p> <p>14 Q. The very first, Page 778.</p> <p>15 A. 778.</p> <p>16 Q. "Using the same method of mesh</p> <p>17 infection, we also experimentally tested Clavé's</p> <p>18 conclusion regarding a correlation between</p> <p>19 infection and polypropylene 'degradation'."</p> <p>20 And what de Tayrac did was they washed</p> <p>21 their mesh with dimethyl sulfoxide and used</p> <p>22 ultrasonic shock, and then analyzed the</p> <p>23 explanted mesh by electron scanning microscope,</p> <p>24 correct?</p> <p>25 A. Correct.</p>	<p>1 actually removed with their dimethyl sulfoxide</p> <p>2 their sonication treatment, so it was already</p> <p>3 gone.</p> <p>4 But what we did was we actually rolled</p> <p>5 one of the fibers, and then took the pieces that</p> <p>6 came off, the same pieces they got off in their</p> <p>7 Figure 1 shown in section B here, Figure 1, we</p> <p>8 ran the infrared of the pieces that actually</p> <p>9 came off, and it wasn't biofilm, it was</p> <p>10 polypropylene.</p> <p>11 Q. Dr. Jordi, do you find any</p> <p>12 methodological flaw in de Tayrac's decision to</p> <p>13 wash the explants used in his experiment with</p> <p>14 dimethyl sulfoxide and using ultrasonic shock?</p> <p>15 A. If you have -- I certainly do. If you</p> <p>16 take a material that's cracked and crazed as we</p> <p>17 saw in our SEMs, and as he shows here in his</p> <p>18 Figure A on Page 778, that material is going to</p> <p>19 be very susceptible to flaking off.</p> <p>20 When I look at 778, Figure A, I see</p> <p>21 what probably is biofilm looking like that cloud</p> <p>22 material on top of the polypropylene, and the</p> <p>23 polypropylene underlying it, which was then</p> <p>24 blown off. Ultrasonic treatment is kind of --</p> <p>25 is a shock treatment, and it's like putting a</p>

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<p>1 bomb on the polypropylene fiber, so it's going 2 to shake off anything that's loose, which it did 3 very beautifully, we know that's what it does, 4 and it did a beautiful job.</p> <p>5 Unfortunately, the stuff that came off 6 wasn't biofilm, are at least it wasn't totally 7 biofilm, it wasn't even 50 percent, the majority 8 of it was polypropylene. At least in my case. 9 I can't speak to their -- without actually doing 10 the IR of the flaked materials in theirs, I 11 can't tell you a percentage, or even an 12 estimate.</p> <p>13 If they had run an IR, which they 14 didn't do -- I'd like to know why they didn't 15 run an IR to see what it was, they just state 16 that it's biofilm with no proof.</p> <p>17 Q. Have you attempted to clean a mesh 18 explant and run the same tests that you ran in 19 Exhibit 1 and Exhibit 2 to determine if your 20 findings are consistent with cleaned explanted 21 mesh?</p> <p>22 A. Cleaned how?</p> <p>23 Q. Let me ask it this way. 24 Is there a way in your training, 25 education, and experience to clean the mesh and</p>	<p>1 Q. My question is; have you ever done 2 that?</p> <p>3 A. No, not to this point.</p> <p>4 Q. And is there any reason other than the 5 FTIR analysis that you've just described on 6 Page 71 and other places in your report --</p> <p>7 A. Correct.</p> <p>8 Q. -- that supports your opinion that 9 de Tayrac is wrong?</p> <p>10 MR. ANDERSON: Objection to form. 11 Go ahead.</p> <p>12 A. I think the infrared speaks for 13 itself. It's -- in my view as a chemist, a 14 polymer chemist, it's pretty locked tight. You 15 can't get polypropylene infrared bands if 16 polypropylene isn't there.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Is that the -- my question is simple. 19 Is that the only information that you have, 20 based on your analysis and work on this case, 21 that confirms for you that de Tayrac is wrong?</p> <p>22 MR. ANDERSON: Objection.</p> <p>23 A. That de Tayrac is wrong. I think I 24 would say yes. I mean we do have other evidence 25 like DSC perhaps, but we have to -- that wasn't</p>
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<p>1 remove biofilms and proteins to allow for the 2 analysis of the explanted mesh as cleaned?</p> <p>3 A. Yes, there is. I've become aware of 4 this since this original work was done. It's 5 sodium hypochlorite.</p> <p>6 Q. And tell me how you use sodium 7 hypochlorite to clean proteins or mesh before 8 you do the analysis?</p> <p>9 A. You just soak the sample, the fiber 10 mesh in this case, in the typically 13 percent 11 chlorine solution of sodium hypochlorite.</p> <p>12 Q. Have you done that?</p> <p>13 A. We did not do that in this work.</p> <p>14 Q. Have you done that at any other time?</p> <p>15 A. No. Not at this point we haven't.</p> <p>16 Q. Have you ever gone -- strike that. 17 Have you ever tried to replicate -- 18 start over one more time.</p> <p>19 Dr. Jordi, have you ever tried to take 20 an explanted mesh, remove biofilm or other 21 protein material, and test it to see the extent 22 to which it had degraded?</p> <p>23 A. I really didn't need to do that in 24 this case because the SEM photographs were so 25 clear.</p>	<p>1 run here either, so I have no data from the 2 paper with which to judge the question.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. You rely on the FTIR analysis in your 5 report in Exhibit Number 1 and Exhibit Number 2 6 in support of your belief that de Tayrac's 7 conclusion that what is seen in the SEM is 8 biofilm to be incorrect, is that fair?</p> <p>9 A. That's fair.</p> <p>10 Q. Back to oxidation.</p> <p>11 Do you have an opinion about what 12 caused the oxidation that you've identified in 13 your report?</p> <p>14 A. I believe there was two major reasons. 15 One was lack of antioxidant, making 16 the polypropylene vulnerable to attack by 17 hydrogen peroxide and other things, from 18 macrophages and so on in the body.</p> <p>19 And the other was environmental stress 20 cracking, which DSC suggests because of the 21 decrease in the Delta H at melt, and the 22 increase in amorphous content of certain of the 23 polymers, and what seems to happen is some 24 samples seem to have a mix of both, and some 25 would be a preponderance of environmental stress</p>

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<p>1 cracking and other damage, and another would be</p> <p>2 caused by classical oxidation mechanism. And</p> <p>3 the majority of samples in this case seemed to</p> <p>4 have both. But it's possible to have just one</p> <p>5 or the other as well.</p> <p>6 Q. Do you have an opinion as to whether</p> <p>7 the polypropylene in the Ethicon mesh -- strike</p> <p>8 that.</p> <p>9 What is it about the human body, the</p> <p>10 biochemistry of the human body, that causes the</p> <p>11 antioxidants to be depleted from the mesh?</p> <p>12 MR. ANDERSON: Objection.</p> <p>13 Go ahead.</p> <p>14 A. I don't know if that's the right</p> <p>15 question. If I can explain?</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Please.</p> <p>18 A. If I were to put polypropylene mesh in</p> <p>19 a solvent like methylene chloride or ethanol or</p> <p>20 propanol or methanol, or any organic solvent,</p> <p>21 the antioxidants would bleed out at a certain</p> <p>22 rate. And the problem here is the mesh is fine,</p> <p>23 so it's a relatively small-ish diameter so</p> <p>24 there's not a lot of distance from the internal</p> <p>25 part of the fiber to the surface. So if I put</p>	<p>1 Doctor, do you have an opinion as to</p> <p>2 what substances in the human body cause the</p> <p>3 Ethicon polypropylene mesh to lose the</p> <p>4 antioxidants that you've identified in your</p> <p>5 report?</p> <p>6 MR. ANDERSON: Objection. Asked and</p> <p>7 answered.</p> <p>8 Go ahead.</p> <p>9 A. It just bleeds, it bleeds out because</p> <p>10 of the nature of the -- we call it blooming in</p> <p>11 the industry. Materials leach out of the</p> <p>12 polymers that they're in, even in air to some</p> <p>13 degree, and then they come on the surface and</p> <p>14 get wiped away. So this would be a slow</p> <p>15 process, which is why I believe the papers</p> <p>16 typically show no initial oxidation. It has to</p> <p>17 be in the body for a while before you see the</p> <p>18 major amounts of these effects.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. How long?</p> <p>21 A. Some of the papers say three months.</p> <p>22 Q. Do you have an opinion about how long</p> <p>23 a mesh has to be in the body before the</p> <p>24 antioxidants are depleted to the point where the</p> <p>25 mesh can degrade?</p>
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<p>1 it in solvent, it's going to bleed out. If I</p> <p>2 put it in the body which is full of lipids,</p> <p>3 cholesterol, phospholipids, cholesterol,</p> <p>4 cholesterol esters, fatty acids, it's going to</p> <p>5 be bleeding out there. But it would bleed out</p> <p>6 in either place. It's not really a phenomenon I</p> <p>7 see that's unique to the human body, it would</p> <p>8 happen either place, and so it just bleeds out</p> <p>9 because of the high -- relative high surface</p> <p>10 area and small diameter.</p> <p>11 Q. Do you have an opinion of what</p> <p>12 specifically it is about the human body that</p> <p>13 causes the Ethicon polypropylene mesh to leak,</p> <p>14 leach its antioxidants?</p> <p>15 A. I don't think -- as I say, I don't</p> <p>16 think that is the right question. It's going to</p> <p>17 leach wherever it is in any solvent.</p> <p>18 It wouldn't leach in water, obviously,</p> <p>19 because it's not soluble, or not wetted by</p> <p>20 water. But anything that will wet it, whether</p> <p>21 it's a fatty acid or whether it's a solvent,</p> <p>22 fatty acid in the body or a solvent, is going to</p> <p>23 cause it to remove, I guess, the fatty -- the</p> <p>24 antioxidants that are bleeding to the surface.</p> <p>25 Q. Let me ask it this way.</p>	<p>1 A. No, we would have to do a study, a</p> <p>2 time study to answer that question, where we</p> <p>3 actually measured -- right now we've just</p> <p>4 measured levels of antioxidant in the samples</p> <p>5 received, the explants and the controls. We</p> <p>6 would have to do a time study to answer that</p> <p>7 question where we'd do three months, six months,</p> <p>8 nine months, a year, five years, however long we</p> <p>9 wanted to do the study, and measure the amount</p> <p>10 of the two antioxidants present as a function of</p> <p>11 time.</p> <p>12 Q. Is the sole basis for your opinion</p> <p>13 that the Ethicon polypropylene mesh at issue in</p> <p>14 this litigation leaches its antioxidants the</p> <p>15 testing that's reflected in Exhibits 1 and 2?</p> <p>16 A. Yes.</p> <p>17 Q. A moment ago I asked you about the</p> <p>18 causes, I think, of degradation, and you said</p> <p>19 oxidation in combination with, in some</p> <p>20 instances, environmental stress cracking?</p> <p>21 A. Correct.</p> <p>22 Q. We also talked earlier about</p> <p>23 mechanical degradation. Is there any evidence</p> <p>24 of mechanical degradation in your work in either</p> <p>25 Exhibits 1 and 2?</p>

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<p style="text-align: right;">Page 70</p> <p>1 A. No. That's a minor player here. If</p> <p>2 any effect, it would have to do during the</p> <p>3 manufacturing phase. When the polymer is put</p> <p>4 through the dye, it will be extruded under</p> <p>5 stress, that's mechanical force, and that will</p> <p>6 tend to shear polymer chains and tend to</p> <p>7 degrade. But that's the only application.</p> <p>8 Certainly in the human body I don't see any</p> <p>9 major application of stress, mechanical stress.</p> <p>10 Q. Okay. So can we confine our</p> <p>11 discussion today of degradation in terms of</p> <p>12 oxidation and environmental stress cracking?</p> <p>13 A. I think so.</p> <p>14 Q. Dr. Jordi, if the mesh antioxidant</p> <p>15 additives remained in the mesh, would the mesh</p> <p>16 be able to perform its function in the body</p> <p>17 without oxidizing?</p> <p>18 A. I think that's suggested in the</p> <p>19 literature, yes.</p> <p>20 Q. Okay. Do you agree with what the</p> <p>21 literature says, that is; if the mesh maintains</p> <p>22 its antioxidants that it's able to perform its</p> <p>23 function in the body as intended?</p> <p>24 A. It certainly would -- I don't know</p> <p>25 that I can answer the question completely, but</p>	<p style="text-align: right;">Page 72</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. What are you reading?</p> <p>3 A. I am looking at -- I'm looking for a</p> <p>4 paper that shows the -- I don't know whether</p> <p>5 it's -- it's either Liebert or Turi, Oswald and</p> <p>6 Turi.</p> <p>7 Q. I'll help you here a little bit.</p> <p>8 (Whereupon, Jordi Exhibit Number 4,</p> <p>9 Liebert, et al study titled</p> <p>10 Subcutaneous Implants of Polypropylene</p> <p>11 Filaments, was marked for</p> <p>12 identification.)</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. Let me show you what's been marked as</p> <p>15 Exhibit Number 4. Exhibit Number 4, is that the</p> <p>16 Liebert study to which you were just referring?</p> <p>17 A. 1976, yes, I believe, yes.</p> <p>18 Q. And in Liebert they studied meshes</p> <p>19 that had been treated with oxidants -- excuse</p> <p>20 me, treated with antioxidants and meshes that</p> <p>21 had not, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And found that those that had been --</p> <p>24 that had antioxidants added to them did not</p> <p>25 degrade like those that did not have</p>
<p style="text-align: right;">Page 71</p> <p>1 it certainly would increase the longevity of the</p> <p>2 product for sure.</p> <p>3 Q. Okay. Do you have an opinion that the</p> <p>4 mesh with the antioxidants that stay there is</p> <p>5 unsafe for its intended purpose without more?</p> <p>6 MR. ANDERSON: Objection as to form.</p> <p>7 Go ahead.</p> <p>8 A. Without more?</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. I'm just trying to narrow the scope</p> <p>11 here. I'm trying to understand. You've told me</p> <p>12 that the literature says that if the</p> <p>13 antioxidants do their job and stay in the mesh,</p> <p>14 that the mesh then is appropriate for use in the</p> <p>15 body to perform the function for which it's</p> <p>16 intended. Is that fair?</p> <p>17 MR. ANDERSON: Objection.</p> <p>18 Mischaracterizes his testimony.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. You can answer it if you can.</p> <p>21 MR. ANDERSON: Well, my objection</p> <p>22 stands. It mischaracterizes his testimony.</p> <p>23 MR. THOMAS: I understand. You said</p> <p>24 it twice. Thank you.</p> <p>25 MR. ANDERSON: Yes, I did.</p>	<p style="text-align: right;">Page 73</p> <p>1 antioxidants, correct?</p> <p>2 A. That's right, showing that, yes.</p> <p>3 Q. Is that the basis -- strike that.</p> <p>4 Is that the literature upon which you</p> <p>5 rely for your statement just a minute ago that</p> <p>6 those meshes with antioxidants in them resist</p> <p>7 degradation?</p> <p>8 A. Well, it's that, and it's my lifetime</p> <p>9 of experience analyzing polypropylenes, and when</p> <p>10 they degrade and when they don't.</p> <p>11 Q. Do you agree with --</p> <p>12 MR. ANDERSON: Are you through with</p> <p>13 your answer?</p> <p>14 THE WITNESS: Not quite.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. I'm sorry.</p> <p>17 A. I'm thinking. I'm sorry.</p> <p>18 Q. You take all the time you need. Never</p> <p>19 meant to interrupt you.</p> <p>20 A. I analyzed -- these are related, but</p> <p>21 they're all polypropylene, analyzed two other</p> <p>22 types of materials over my experience that I can</p> <p>23 recall.</p> <p>24 One was a seating material at a</p> <p>25 stadium, that was involved in a stadium seating</p>



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<p>1 in Japan, 100,000 seat stadium. The seats in 2 one year from installation turned to dust and 3 blew away. So they had sent me some retains, 4 and I had to analyze it, and the polypropylene 5 was not stabilized. And so that's part of my 6 lifetime of experience.</p> <p>7 Another case, the client was suing a 8 motorcycle manufacturer because -- for a 9 defective gas tank. But he'd hit a brick wall 10 at a very high rate of speed, I don't remember 11 the exact, 75, 80 miles an hour, and the gas 12 tank ruptured and exploded. And so they were 13 blaming the manufacturer. So I had to analyze a 14 bit of that. In that case the stabilizers were 15 present. And the point was no gas tank is going 16 to survive hitting a brick wall at 75, 80 miles 17 an hour, so -- even though the stabilizer was 18 there. So it wasn't degraded, molecular 19 weight-wise, it wasn't degraded, the 20 antioxidants were there.</p> <p>21 And in the other case, it turned to 22 dust and blew away, and the antioxidants were 23 not present.</p> <p>24 So when I see a lack of antioxidant in 25 essentially basically all these samples, by both</p>	<p>1 their free form. But the Fenton reaction is 2 well-known.</p> <p>3 Q. You call it the Fenton reaction? 4 A. Fenton reaction, yes.</p> <p>5 Q. Okay. If hydrogen peroxide was the 6 cause of the degradation of the polypropylene 7 mesh, would there be a change in the molecular 8 structure of polypropylene? 9 A. Repeat the question, please? I'm 10 sorry.</p> <p>11 Q. If the hydrogen peroxide that you 12 described was the cause of the degradation in 13 the polypropylene mesh, would there be a change 14 in the chemical structure of the polypropylene 15 mesh? 16 A. That's right, there would be.</p> <p>17 Q. If there was a free radical that 18 degraded the polypropylene mesh, would there be 19 a change in the chemical construction of the 20 polypropylene mesh? 21 A. Yes. You would be inserting oxygen 22 into the chain in the form of either ketone, 23 aldehyde, hydroxide.</p> <p>24 Q. And the free ferrous ion which you 25 referred to as the Fenton?</p>
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<p>1 PYMS and LCMS, it tells me the polymer is 2 exceedingly susceptible to oxidation by hydrogen 3 peroxide, which it would be partially protected 4 from if antioxidants were still there, but 5 they're not there.</p> <p>6 Q. Okay. Is it your opinion that 7 hydrogen peroxide is the material that attacked 8 the mesh that caused it to degrade as is 9 reflected in Exhibits 1 and 2? 10 A. Well, in the body there are things 11 like ferrous ion, for example, and if -- I can't 12 answer the question with a simple answer 13 because, again, there's multiple causes.</p> <p>14 If there's any free ferrous ion around 15 you'll get what's called a Fenton reaction, 16 which converts hydrogen peroxide to hydroxyl 17 radicals, which are more damaging than the 18 hydrogen peroxide to begin with in causing 19 degradation of the polypropylene. It's a free 20 radical initiator step.</p> <p>21 So if there is, you know, bleeding 22 perhaps, that can be a source of iron, and if 23 there's some ferrous ion around -- of course it 24 has to be free ferrous ion, the body needs 25 protein to bind iron, because it's dangerous in</p>	<p>1 A. It's not just a free -- if you would 2 like I'll give you the reaction. Do you want 3 that? 4 Q. Yes.</p> <p>5 A. <math>\text{Fe}^{2+}</math> plus hydrogen peroxide goes to, 6 an arrow, <math>\text{Fe}^{3+} + \text{HO}^-</math> -- that's hydroxide, that's 7 harmless, but here's the problem -- <math>+\text{HO}^\cdot</math>, which 8 is the radical, hydroxy radical, that is many 9 more times damaging to polypropylene than the 10 initial hydrogen peroxide.</p> <p>11 Q. Okay. 12 A. Now, I can't sort out which one is -- 13 Q. That's fine. You're consulting a 14 paper there. What's the paper you're 15 consulting? 16 A. "Mechanisms of polymer degradation in 17 implantable devices" by Williams.</p> <p>18 Q. That's David Williams? 19 A. David Williams.</p> <p>20 Q. That's the one cited in your -- 21 A. Yes, sir.</p> <p>22 Q. Okay. The last reaction you described 23 is called the Fenton reaction, is that right? 24 A. Right.</p> <p>25 Q. Does the Fenton reaction causing</p>

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<p>1 degradation of polypropylene alter the chemical 2 structure of the polypropylene? 3 A. Does the hydroxide -- or the Fenton 4 reaction cause, is that what you're asking. 5 Q. Yes. 6 A. Sure it does, because that's the 7 production of the hydroxy radicals which causes 8 the actual change. 9 Q. Any other potential sources of 10 oxidation to the polypropylene mesh given the 11 leaching of antioxidants that you've described? 12 MR. ANDERSON: Objection as to form. 13 Go ahead. 14 A. You could also have what's called a 15 more general version of the Fenton reaction, 16 would be the Haber-Weiss, H-A-B-E-R - W-E-I-S-S, 17 reaction. 18 BY MR. THOMAS: 19 Q. Are you consulting the Williams 20 article again? 21 A. Yes. That would be include cuprous 22 ion as well as ferrous ion, could include 23 titanium is another one, titanium 3 or vanadium 24 4 is another possibility. Those are not 25 commonly found, we're not going to worry about</p>	<p>1 A. Those are described in actual tests in 2 the Dr. Müller book, timed experiments. 3 Q. Do you know? 4 A. Well, it depends on the temperature. 5 And it varies with the environment, the oxygen 6 environment and the temperature actually used. 7 Some are run at 200 degrees, some are run at 8 100 degrees. 9 Q. Do you know the temperature at which 10 the polypropylene that's used in the Ethicon 11 mesh will degrade? 12 A. I know in general terms that the 13 higher the temperature, the faster it will 14 degrade. That's what I know. Which is 15 uniformly true. 16 Q. Do you have an opinion as you sit here 17 today of the temperature at which the Ethicon 18 mesh used in the TVT device will degrade? 19 A. Without testing, no. And it would 20 depend on whether the antioxidants are there or 21 not, that will affect the temperature. 22 Q. Is it possible to measure the amount 23 of hydrogen peroxide that is in a person around 24 the mesh implant? 25 A. We have techniques that will allow us</p>
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<p>1 those in the body. 2 Q. Titanium and vanadium aren't going to 3 be found in the body, are they? 4 A. No. It's cuprous and ferrous. 5 Q. Are all of the potential methods of 6 degradation for the polypropylene mesh that 7 you've identified in the human body in the 8 Williams article that you're consulting? 9 A. Well, they're certainly in there. 10 Other authors describe that as well. 11 Q. Okay. Are there any other methods 12 described by other authors? 13 A. Other methods? 14 Q. Yes. Have we covered all the bases in 15 the Williams article? 16 A. Well, you could get R., which is the 17 radical form of polypropylene, just from heat to 18 some degree, so that's why heat would cause 19 radical formation also. 20 Q. How much heat would require -- 21 A. I don't think the human body, we'd 22 have to worry too much in the human body. We're 23 talking processing now. 24 Q. How much heat does it take to degrade 25 polypropylene, do you know?</p>	<p>1 to measure hydrogen peroxide. We have hydrogen 2 peroxide test strips, for example, but you can't 3 stick those into an implant very well. So I 4 don't know, I've never seen it talked about or 5 done anywhere. 6 Q. Are you able to test for the presence 7 of hydrogen peroxide on the explants that you 8 analyzed? 9 A. You could try to use those test strips 10 and see if -- the strips turn blue if -- but 11 likely, it's been stored in the formaldehyde in 12 getting to us, so it's all going to be washed 13 off anyway. 14 Q. Do you know, as you sit here today, 15 whether you can test the explanted mesh samples 16 that you received to determine the presence of 17 any of the materials that you've just identified 18 that could contribute to the degradation of the 19 mesh? 20 A. Well, no, I don't think so, not as 21 received. 22 Q. You don't know, or you don't think you 23 could? 24 A. You can't, because -- 25 Q. I didn't hear you. I'm sorry. You</p>

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<p>1 cannot?</p> <p>2 A. Cannot.</p> <p>3 Q. Thank you.</p> <p>4 A. Because it's not there, it's been</p> <p>5 treated with formaldehyde when we get it, so</p> <p>6 it's not the way it was in the body --</p> <p>7 Q. Okay.</p> <p>8 A. -- at the time of excision.</p> <p>9 Q. So is it fair to understand that it's</p> <p>10 your opinion that you're not able to test these</p> <p>11 mesh explants for materials that may have been</p> <p>12 in the body that you believe caused or</p> <p>13 contributed to the degradation of the mesh?</p> <p>14 MR. ANDERSON: Objection to form.</p> <p>15 Materials in the body, or chemicals in</p> <p>16 the body?</p> <p>17 MR. THOMAS: Thank you, Ben.</p> <p>18 MR. ANDERSON: Just to be clear.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Doctor, is it fair to understand it's</p> <p>21 your opinion that because of the placement of</p> <p>22 the explants in formaldehyde, that one is unable</p> <p>23 to test for chemicals in the body that may have</p> <p>24 caused or contributed to the degradation of the</p> <p>25 mesh?</p>	<p>1 of metals that would be the catalyst for the</p> <p>2 Haber-Weiss reaction or the Fenton reaction.</p> <p>3 Q. If you had that information, how would</p> <p>4 you use that to determine the extent to which</p> <p>5 those chemicals caused or contributed to the</p> <p>6 degradation of the mesh?</p> <p>7 A. Well, the greater the concentration of</p> <p>8 the iron and copper, copper 2 and iron -- copper</p> <p>9 1 and iron 2, the greater the damage would be.</p> <p>10 Q. Okay.</p> <p>11 A. It should correlate. But it's</p> <p>12 complicated, because if those metals were tied</p> <p>13 up by the typical proteins in the body that are</p> <p>14 supposed to tie up copper and iron so they are</p> <p>15 not -- they don't kill us, you have to figure</p> <p>16 out a way to -- and as I sit here, this is just</p> <p>17 research, I'm unable to answer the question</p> <p>18 completely, I would have to be sure that the</p> <p>19 iron we determined was free ferrous ion in the</p> <p>20 body and free cuprous, or it wouldn't be</p> <p>21 damaging even if present.</p> <p>22 Sorry, that's my answer.</p> <p>23 Q. Okay. Let me see if I can finish</p> <p>24 this.</p> <p>25 Is it fair to understand, Doctor, as</p>
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<p>1 A. That question would require a lot of</p> <p>2 research. But it's possible, for example, that</p> <p>3 we could -- certainly we could look for iron in</p> <p>4 the tissue, or we could look for copper in the</p> <p>5 tissue, which would be consistent with the</p> <p>6 Haber-Weiss reaction, which would have produced</p> <p>7 the hydrogen peroxide in the first place. So we</p> <p>8 could see telltale signs. In that sense, we</p> <p>9 might be able to see something.</p> <p>10 Q. Doctor, as you sit here today, is</p> <p>11 there a test that you know of that could be</p> <p>12 performed on these explanted meshes to determine</p> <p>13 which chemical substance in the body caused or</p> <p>14 contributed to any degradation of this mesh?</p> <p>15 A. If it's hydrogen peroxide produced in</p> <p>16 the macrophages, we can't test for it because</p> <p>17 it's not there.</p> <p>18 Q. Okay. Anything else?</p> <p>19 A. If it's caused by the Fenton reaction</p> <p>20 or the Haber-Weiss, yes, we could take that</p> <p>21 tissue, and we could dissolve it, and then run</p> <p>22 ion chromatography and determine parts per</p> <p>23 billion levels of iron and the copper.</p> <p>24 Q. What would that tell you?</p> <p>25 A. It would tell us the potential levels</p>	<p>1 you sit here today you don't know of a test that</p> <p>2 would enable you to determine which chemicals in</p> <p>3 the body caused or contributed to any</p> <p>4 degradation of the mesh explant samples?</p> <p>5 A. No. We just know that macrophages</p> <p>6 have been shown to -- in superoxide and hydrogen</p> <p>7 peroxide.</p> <p>8 Q. Okay. You said "no" to my question.</p> <p>9 A. I'm sorry. Correct.</p> <p>10 Q. Is it true, is it fair to say that, as</p> <p>11 you sit here today, that you don't know of any</p> <p>12 tests that would allow you to determine which</p> <p>13 chemicals in the body may have caused or</p> <p>14 contributed to any degradation of the mesh</p> <p>15 explant samples?</p> <p>16 A. Again, from my reading the literature</p> <p>17 and seeing the production of hydrogen peroxide</p> <p>18 and superoxide, that has to be one of the</p> <p>19 mechanisms, and the other ones could be. I</p> <p>20 don't know how to answer the question.</p> <p>21 Q. But the question is; it's fair to</p> <p>22 understand, as you sit here today, that you do</p> <p>23 not know of any test that you could perform to</p> <p>24 determine which chemicals in the body may have</p> <p>25 caused or contributed to any degradation of the</p>

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<p>1 polypropylene mesh in these explants? You don't 2 know of one?</p> <p>3 A. Seeing the oxidation, I couldn't tell 4 you whether it was caused by the Fenton 5 reaction, the Haber-Weiss reaction, or hydrogen 6 peroxide, that's true, if that's what you want.</p> <p>7 Q. Thank you.</p> <p>8 Or any other substance, there's not a 9 test that you can do to tell us what caused it?</p> <p>10 A. No. All I can say is I'm looking at 11 the fact of the degradation. It had to happen, 12 so I'd be looking for -- as to what specifically 13 caused it, I have to agree.</p> <p>14 Q. Thank you.</p> <p>15 A. I can't answer.</p> <p>16 MR. THOMAS: We can take a quick break 17 if you don't mind.</p> <p>18 (Whereupon, a recess was taken from 19 11:06 a.m. to 11:15 a.m.)</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Doctor, what is environmental stress 22 cracking?</p> <p>23 A. Environmental stress cracking is the 24 degradation of a polymer from imbibing, or the 25 absorption of materials, in this case like</p>	<p>1 amount of crystallinity goes down. Delta H of 2 melt goes down, the percent crystallinity goes 3 down, the percent amorphous goes up, which then 4 that material, the amorphous material, is what 5 is susceptible to environmental stress cracking.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. Doctor, do you have an opinion in this 8 case as to whether the mesh explants that you 9 analyzed show environmental stress cracking?</p> <p>10 A. I think as one of the components I 11 have an opinion, because we saw a drop in the 12 Delta H at melt, of the explants.</p> <p>13 Q. Is it your opinion that the drop in 14 the Delta H in the DSC testing is proof of 15 environmental stress cracking?</p> <p>16 A. It's just like the lack of 17 antioxidants. It's consistent with, it's not by 18 itself proof of. But it's proof of the 19 susceptibility of the polymer to environmental 20 stress cracking.</p> <p>21 Then I have to go back still, 22 ultimately back to the SEMs, because the fact is 23 not in question. It's occurring, we can see it. 24 The question is why, and that way we have to -- 25 now we have to look at a series of data to make</p>
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<p>1 cholesterol, cholesterol esters, fatty acids, 2 into the interstitial space between the polymer 3 chains which causes it to swell, creating 4 stress, which eventually ruptures some of the 5 polymer chains, causing degradation.</p> <p>6 Q. Is it your opinion in this case that 7 the mesh explants that you analyzed exhibit 8 environmental stress cracking?</p> <p>9 A. Sorry. Repeat the question, please?</p> <p>10 Q. Is it your opinion in this case that 11 the mesh explants that you analyzed show 12 environmental stress cracking?</p> <p>13 MR. ANDERSON: Objection. Asked and 14 answered.</p> <p>15 Go ahead.</p> <p>16 A. When I look at SEM photographs and see 17 the cracking, I can't tell just from looking at 18 the cracking whether it was oxidative damage or 19 environmental stress cracking that caused that 20 damage, or a combination of both.</p> <p>21 DSC is one of the best techniques to 22 suggest that, because we can measure the melt 23 point, and we can measure the Delta H at melt 24 which correlates to the amount of crystallinity. 25 So as the Delta H of melting goes down, the</p>	<p>1 our best judgment. I think in many cases the 2 damage is caused by both.</p> <p>3 Q. So just so I'm clear, your opinion 4 that the mesh that you've analyzed in the 5 explants has undergone environmental stress 6 cracking is due to your visual observation on 7 the SEM images and the DSC data, correct?</p> <p>8 A. Right.</p> <p>9 Q. Is there any other information that 10 you determined from your report, or your work in 11 this case, that you rely upon for your opinion 12 that the explanted mesh underwent environmental 13 stress cracking?</p> <p>14 A. Any other data from my report, that 15 was the question?</p> <p>16 Q. Yes.</p> <p>17 A. No.</p> <p>18 Q. All right. Do you agree that pelvic 19 organ prolapse is well-known for its high 20 resistance to environmental stress cracking?</p> <p>21 A. Yes. But the fact of the matter is 22 the Delta H is going down, so something is 23 causing that amorphous region to increase.</p> <p>24 Q. And the Delta H you're talking about 25 is the melting point as measured by the DSC</p>

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<p>1 measurements, correct?</p> <p>2 A. The melting point goes down, and the</p> <p>3 Delta H at melt goes down. And again, there's</p> <p>4 variability from sample to sample. So some</p> <p>5 samples have more component of potential, I'll</p> <p>6 describe it as potential environmental stress</p> <p>7 cracking, and other samples from less potential.</p> <p>8 The same way I would describe the lack of</p> <p>9 antioxidant to be potential oxidation.</p> <p>10 In all cases we are seeing the</p> <p>11 degradation through SEM of the polypropylene.</p> <p>12 That's just a fact. And we know it's</p> <p>13 polypropylene because the infrared spectrum is</p> <p>14 that of polypropylene, the flakes.</p> <p>15 Q. What's crazing?</p> <p>16 A. Small cracks.</p> <p>17 Q. What does crazing have to do with</p> <p>18 environmental stress cracking?</p> <p>19 A. Well, it's the start of the process.</p> <p>20 When you have a little bit of cholesterol ester</p> <p>21 you have just little cracks, little start, it's</p> <p>22 moving in, the process is beginning.</p> <p>23 Q. Are you familiar with a concept known</p> <p>24 as crack initiation?</p> <p>25 A. That's what crazing does, is initiates</p>	<p>1 fatty acids and the like, then the process would</p> <p>2 be more rapid than they would if there weren't</p> <p>3 as much cholesterol, cholesterol esters in a</p> <p>4 given patient. That depends on the patient's</p> <p>5 disease state, for example, their weight.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. Do you have an opinion in this case</p> <p>8 about the expected rate of crack propagation in</p> <p>9 the mesh implanted in Carolyn Lewis?</p> <p>10 A. No.</p> <p>11 Q. Do you have an opinion about the</p> <p>12 expected mesh -- excuse me, crack propagation of</p> <p>13 the mesh implanted in Linda Batiste?</p> <p>14 A. Well, the fact of the matter is I can</p> <p>15 see the cracks, I'm looking at them with SEM.</p> <p>16 That's all I can say.</p> <p>17 Q. Very specific question.</p> <p>18 Do you have an opinion about the</p> <p>19 expected time for the crack propagation in Linda</p> <p>20 Batiste?</p> <p>21 A. No, I don't.</p> <p>22 Q. Are you able to analyze the mesh</p> <p>23 explants and determine how long the mesh has</p> <p>24 been cracked?</p> <p>25 A. No. Just the fact that it is.</p>
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<p>1 the forming of the larger cracks.</p> <p>2 Q. So when you have smaller cracks and</p> <p>3 things get in there, then the cracks get bigger?</p> <p>4 A. Basically.</p> <p>5 Q. What's crack propagation?</p> <p>6 A. Once a material starts to crack, it's</p> <p>7 like a rip in a garment, it's going to just --</p> <p>8 once the rip starts, it's easier to continue it.</p> <p>9 Q. Are you familiar with a concept known</p> <p>10 as fast crack propagation?</p> <p>11 A. No, I'm not.</p> <p>12 Q. Do you know the extent to which</p> <p>13 environmental stress cracking in polypropylene</p> <p>14 could be expected to be slow or fast, or there</p> <p>15 in small forms forever? Do you have any idea of</p> <p>16 the relative -- strike that. That's a terrible</p> <p>17 question.</p> <p>18 Doctor, do you have any ideas about</p> <p>19 the expected progress of crack propagation in</p> <p>20 polymers?</p> <p>21 MR. ANDERSON: Objection to form.</p> <p>22 Go ahead.</p> <p>23 A. It would depend on the environment</p> <p>24 again. Again, if some patients have more,</p> <p>25 there's more cholesterol esters that can get in,</p>	<p>1 Q. Are you able to analyze the mesh</p> <p>2 explants that you've reviewed in this case and</p> <p>3 determine or measure the extent of the cracking?</p> <p>4 A. Well, visually it's quite obvious</p> <p>5 that --</p> <p>6 Q. I'm talking about quantitatively.</p> <p>7 A. There is no way to do that short of</p> <p>8 looking at the pictures, that I'm aware of. I</p> <p>9 don't know anybody using a scale.</p> <p>10 Q. Do you have an opinion in this case,</p> <p>11 first of all the Carolyn Lewis case, about the</p> <p>12 extent to which any degradation in her -- strike</p> <p>13 that.</p> <p>14 Do you have an opinion in the Carolyn</p> <p>15 Lewis case about the extent to which any</p> <p>16 environmental stress cracking impacts the</p> <p>17 functionality of the polypropylene mesh for its</p> <p>18 intended purpose?</p> <p>19 A. Let me look at the -- I have to look</p> <p>20 at the DSC data.</p> <p>21 Q. This is very specific. This is</p> <p>22 Carolyn Lewis.</p> <p>23 A. Correct.</p> <p>24 (Witness reviewing document.)</p> <p>25 A. Okay. What's the question, please,</p>

24 (Pages 90 to 93)



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<p>1 again?</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Do you have an opinion in the Carolyn</p> <p>4 Lewis case about the extent to which any</p> <p>5 environmental stress cracking impacts the</p> <p>6 functionality of the polypropylene mesh for its</p> <p>7 intended purpose?</p> <p>8 A. I do not.</p> <p>9 Q. Do you have an opinion in the Carolyn</p> <p>10 Lewis case about the extent to which any</p> <p>11 oxidation impacts the functionality of the</p> <p>12 polypropylene mesh for its intended purpose?</p> <p>13 MR. ANDERSON: Objection as to form.</p> <p>14 A. Of oxidation effects the --</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Correct.</p> <p>17 A. Now I have to go through and look and</p> <p>18 see if --</p> <p>19 (Witness reviewing document.)</p> <p>20 A. Well, the infrared spectrum on Page 71</p> <p>21 is a Carolyn Lewis sample. It has a carbonyl</p> <p>22 band, so the little band that's in front of the</p> <p>23 amide 1 is a sign of oxidation.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. That's not my question, Doctor. Let</p>	<p>1 question.</p> <p>2 Q. Based upon your review of the mesh in</p> <p>3 this case and your analysis in this case, tell</p> <p>4 me how the oxidation of the mesh in Carolyn</p> <p>5 Lewis impacts the functionality of the</p> <p>6 polypropylene mesh for its intended purpose?</p> <p>7 How does it do it?</p> <p>8 A. When you get ketones in the polymer,</p> <p>9 aldehydes in the polymer as reflected in these</p> <p>10 carbonyls, you -- that leads to ultimately to</p> <p>11 chain -- what we call chain beta scission, chain</p> <p>12 scission, which is degradation. And besides, it</p> <p>13 causes embrittlement in its own right. Very low</p> <p>14 levels of oxygen incorporated into polypropylene</p> <p>15 causes a material to become rigid which is</p> <p>16 classic of this.</p> <p>17 Q. What is it about your work in this</p> <p>18 case that causes you to have the opinion that</p> <p>19 the oxidation of the mesh in Carolyn Lewis</p> <p>20 impacts the functionality of that mesh for its</p> <p>21 intended purpose?</p> <p>22 A. Oxidation is bad. We see it.</p> <p>23 Q. Okay. Are you able to measure the</p> <p>24 amount of oxidation that occurred in Carolyn</p> <p>25 Lewis quantitatively?</p>
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<p>1 me ask it again. Very specific question.</p> <p>2 Do you have an opinion in the Carolyn</p> <p>3 Lewis case about the extent to which any</p> <p>4 oxidation impacts the functionality of the</p> <p>5 polypropylene mesh for its intended purpose? Do</p> <p>6 you have a specific opinion in that regard?</p> <p>7 A. My opinion would be it appears</p> <p>8 oxidized, so yeah, it would be degraded.</p> <p>9 Q. Does it have any have oxidation -- do</p> <p>10 you have an opinion about whether the Carolyn</p> <p>11 Lewis mesh explant has oxidation that impacts</p> <p>12 the functionality of the polypropylene mesh for</p> <p>13 its intended purpose?</p> <p>14 A. Any oxidation is bad. I see carbonyl</p> <p>15 is oxidation, so yes, my answer is yes, I have</p> <p>16 an opinion.</p> <p>17 Q. What is the opinion?</p> <p>18 A. It's damaged.</p> <p>19 Q. How does the damage that you observed</p> <p>20 affect the ability of the polypropylene mesh to</p> <p>21 function in its intended purpose?</p> <p>22 A. Well, something had to cause it to</p> <p>23 have it removed. I'm looking at the pictures,</p> <p>24 it's flaking, I'm looking at the oxidation, it's</p> <p>25 oxidized. I don't know how else to answer the</p>	<p>1 A. No.</p> <p>2 Q. Can you tell me anything more than</p> <p>3 oxidation is bad in support of your opinion that</p> <p>4 the work in this case shows that the mesh</p> <p>5 implanted in Ms. Lewis was not able to perform</p> <p>6 its intended function?</p> <p>7 A. The antioxidants were missing. The</p> <p>8 material is not protected. I think we see -- we</p> <p>9 go over and look at EDX results, if I can</p> <p>10 find --</p> <p>11 (Witness reviewing document.)</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. You can look all you want to. Do you</p> <p>14 want to continue your answer? I don't think you</p> <p>15 answered my question, but you can do whatever</p> <p>16 you think you need to do.</p> <p>17 MR. ANDERSON: He's trying to ask you</p> <p>18 what about the oxidation in Carolyn Lewis, in</p> <p>19 your opinion, affects the function of the device</p> <p>20 for its intended purpose.</p> <p>21 A. All oxidation affects the function.</p> <p>22 MR. ANDERSON: How is what he's asking</p> <p>23 you.</p> <p>24 A. It makes it more rigid. It makes it</p> <p>25 more brittle eventually. It causes it to flake.</p>

25 (Pages 94 to 97)



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<p>1 BY MR. THOMAS:</p> <p>2 Q. How much oxidation is required for the</p> <p>3 mesh to be more rigid?</p> <p>4 A. I can't answer that question sitting</p> <p>5 here, but it's not very much from reading the</p> <p>6 literature. 1 percent increased oxygen would</p> <p>7 probably do it.</p> <p>8 Q. How much oxidation is required to make</p> <p>9 the polypropylene more brittle?</p> <p>10 A. It's a process. It's not a single</p> <p>11 point. So I felt this material in my fingers, I</p> <p>12 could feel the rigidity in it compared to the</p> <p>13 straight.</p> <p>14 Q. Very simple question. How much</p> <p>15 oxidation is required, Doctor?</p> <p>16 A. I don't know.</p> <p>17 Q. How many oxidation is required to</p> <p>18 cause the polypropylene to flake?</p> <p>19 A. Anywhere from none to a lot, because</p> <p>20 it depends if it was environmental stress</p> <p>21 cracking you wouldn't necessarily have</p> <p>22 oxidation for environmental stress cracking, or</p> <p>23 it could be totally related to oxidation, or it</p> <p>24 could be a mix.</p> <p>25 Q. Dr. Jordi, you report in Exhibit 1 and</p>	<p>1 to the extrusion lines, or the grain of the</p> <p>2 mesh?</p> <p>3 A. Correct.</p> <p>4 Q. Have you analyzed the extent to which</p> <p>5 perpendicular cracking is consistent with the</p> <p>6 chemical structure of the mesh?</p> <p>7 A. Repeat the question, please?</p> <p>8 Q. Have you analyzed the extent to which</p> <p>9 perpendicular cracking is consistent with the</p> <p>10 chemical structure of the mesh?</p> <p>11 MR. ANDERSON: Objection as to form.</p> <p>12 Go ahead.</p> <p>13 A. When you put a material through the</p> <p>14 dye, you'll be aligning the polymer chains along</p> <p>15 the line of the fiber so that only -- you</p> <p>16 basically only have London-London forces of the</p> <p>17 CH<sub>2</sub> groups and CH<sub>3</sub> groups in the polymer</p> <p>18 backbone holding the polymer together, so it</p> <p>19 will be more easily cracked -- if you bend it</p> <p>20 it's going to tend to crack vertically to the</p> <p>21 direction of the fiber.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Okay. Is that something you studied</p> <p>24 before I asked you the question, or you just</p> <p>25 answered that question based upon your</p>
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<p>1 2 the observation of cracking perpendicular to</p> <p>2 the extrusion lines in the mesh?</p> <p>3 A. Yes.</p> <p>4 Q. And what are extrusion lines?</p> <p>5 A. Well, you just can see them in the --</p> <p>6 I think they're little -- probably caused by</p> <p>7 miniature, if you want to call it, defects in</p> <p>8 the dye.</p> <p>9 Page 25 is a typical example. You can</p> <p>10 see the lines moving along the line of</p> <p>11 extrusion.</p> <p>12 Q. Extrusion is a process by which the</p> <p>13 fibers are formed?</p> <p>14 A. I believe so, yes.</p> <p>15 Q. Are you familiar with the extrusion</p> <p>16 process?</p> <p>17 A. Not a lot.</p> <p>18 Q. Okay.</p> <p>19 A. I'm more an analyst.</p> <p>20 Q. Are you comfortable with calling the</p> <p>21 extrusion lines the grain of the fiber?</p> <p>22 A. Sure.</p> <p>23 Q. Okay. And when we talk about the</p> <p>24 perpendicular cracks, we're talking about the</p> <p>25 cracking that you observed being perpendicular</p>	<p>1 knowledge?</p> <p>2 A. Based on my knowledge.</p> <p>3 Q. Okay. Did you study, as a part of</p> <p>4 your analysis of this case, the extent to which</p> <p>5 cracking would be expected along the grain or</p> <p>6 extrusion lines of the mesh as compared to the</p> <p>7 perpendicular angle that's called out in your</p> <p>8 report?</p> <p>9 MR. ANDERSON: Objection as to form.</p> <p>10 A. Again, I have to have it repeated.</p> <p>11 Sorry.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Did you study, as a part of your</p> <p>14 analysis of this case, the extent to which</p> <p>15 cracking would be expected along the grain or</p> <p>16 extrusion lines of the mesh as compared to the</p> <p>17 perpendicular angle that's called out in your</p> <p>18 report?</p> <p>19 A. Well, what's called out in my report</p> <p>20 was what we observed.</p> <p>21 Did I study differences? It's not a</p> <p>22 perfect thing. You can see cracks in other</p> <p>23 directions, too, sometimes, it's just a majority</p> <p>24 seems to be in the vertical.</p> <p>25 Q. Okay.</p>

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<p>1 A. And furthermore, you can see these --</p> <p>2 the grain, as you call it, is running right</p> <p>3 through these cracks, so that's further</p> <p>4 information to suggest that these -- this</p> <p>5 cracked region is not biofilm, it's</p> <p>6 polypropylene, because it's got the same grain</p> <p>7 in it the original polypropylene did in the</p> <p>8 cracked pieces. If it was biofilm, those marks</p> <p>9 should go away. They don't, they're there.</p> <p>10 Q. Have you analyzed the issue of</p> <p>11 environmental stress cracking to determine</p> <p>12 whether environmental stress cracks would run</p> <p>13 with the extrusion lines or the grain as opposed</p> <p>14 to the perpendicular manner in which you call</p> <p>15 out in your report?</p> <p>16 A. Have I analyzed that? No.</p> <p>17 Q. The crazing that you've talked about</p> <p>18 are the areas in the mesh that are furthest away</p> <p>19 from the crystals in the mesh, is that fair, in</p> <p>20 the amorphous regions?</p> <p>21 A. In the amorphous regions, yes.</p> <p>22 Q. And the crazing that you've talked</p> <p>23 about is the small cracks that form in this</p> <p>24 amorphous region, correct?</p> <p>25 A. Yes.</p>	<p>1 come apart in the amorphous region. They don't</p> <p>2 have as much force holding them together. You</p> <p>3 have to literally rupture chemical bonds.</p> <p>4 I don't see what you're saying, I'm</p> <p>5 sorry.</p> <p>6 Q. So is it your testimony that to have</p> <p>7 the oxidation or environmental stress cracking</p> <p>8 necessary to cause the cracking on Page 40 in</p> <p>9 Figure 44 of your report, Exhibit 1, requires a</p> <p>10 rupture of the chemical bond?</p> <p>11 A. I would think that would be true on</p> <p>12 the surface, yes.</p> <p>13 Q. Okay.</p> <p>14 A. Has to be.</p> <p>15 Q. And every place that you see this</p> <p>16 cracking in the scanning electron microscopy,</p> <p>17 the images that you've talked about, in order to</p> <p>18 get the cracking that you describe shown in the</p> <p>19 SEM images requires a breaking of the chemical</p> <p>20 bond; fair?</p> <p>21 A. I think so.</p> <p>22 Q. Let's go to your report, Exhibit</p> <p>23 Number 1. Let's go to the PYMS data.</p> <p>24 MR. ANDERSON: Page 80 you're showing?</p> <p>25 MR. THOMAS: Page 80.</p>
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<p>1 Q. Knowing what you do about</p> <p>2 polypropylene, and the chemical structure of it,</p> <p>3 and the crazing that you've just described,</p> <p>4 wouldn't it be more likely that any</p> <p>5 environmental stress cracking would occur with</p> <p>6 the grain or along the extrusion lines of that</p> <p>7 mesh as opposed to perpendicular to the mesh?</p> <p>8 A. The -- if you -- well, first of all,</p> <p>9 the fact of the matter is it's vertical to it.</p> <p>10 I mean that's just a fact for the vast majority</p> <p>11 of them.</p> <p>12 Q. I'm asking you based upon your</p> <p>13 knowledge as a biochemist, your knowledge of</p> <p>14 polypropylene, and your knowledge of the</p> <p>15 chemical structure, and the way that you've</p> <p>16 described the environmental stress cracking as</p> <p>17 we've been through it, isn't it more logical to</p> <p>18 conclude that environmental stress cracking</p> <p>19 would occur along the grain or the extrusion</p> <p>20 lines as opposed to perpendicular to those</p> <p>21 lines?</p> <p>22 A. If you wanted -- if you picture long</p> <p>23 chains going this way of polymer, and then you</p> <p>24 bent it this way, then it's going to tend to</p> <p>25 crack here because those chains are going to</p>	<p>1 A. Okay.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Tell me what the PYMS technique is.</p> <p>4 A. Stands for pyrolysis mass</p> <p>5 spectroscopy. The sample is heated, and until</p> <p>6 it fractures the bonds in the polymer releasing</p> <p>7 everything, small molecules and so on, and then</p> <p>8 those fragments are put through a GC column,</p> <p>9 then they're monitored by a mass spectrometer.</p> <p>10 We tend to do a two step method as</p> <p>11 well where we heat the sample to 300C, which</p> <p>12 tends not to fragment the polymer, and that</p> <p>13 releases additives so we can see additives</p> <p>14 without being overwhelmed by polymer fragments.</p> <p>15 One of the disadvantages of a PYMS by</p> <p>16 itself is that when you burn the polymer, in</p> <p>17 this case polypropylene, you get a massive</p> <p>18 amount of polypropylene fragment ions which</p> <p>19 tends to overwhelm the ability of a detector to</p> <p>20 sense sometimes certain ions, like the</p> <p>21 antioxidants, like Santonox, at least at the</p> <p>22 levels that we want to detect it at.</p> <p>23 Q. As I understand your report and your</p> <p>24 earlier discussion, you used the PYMS analytical</p> <p>25 technique to determine the extent to which</p>

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<p>1 additives in the Ethicon polypropylene mesh are</p> <p>2 present?</p> <p>3 A. That's right. I mean that's one of</p> <p>4 two. We use the LCMS as well.</p> <p>5 Q. Start with this one. Tell me how you</p> <p>6 do that.</p> <p>7 A. How you determine --</p> <p>8 Q. Right.</p> <p>9 A. You -- well, you would first, if</p> <p>10 you're looking for Santonox R, you would shoot a</p> <p>11 standard of Santonox R, and then you would look</p> <p>12 for the ions that you get. Santonox R gives</p> <p>13 ions at 358 and 343 atomic mass units, so you</p> <p>14 would plot those ions and look at them as shown</p> <p>15 on figure -- well, the ions aren't shown in</p> <p>16 Figure 82, but the chromatogram is.</p> <p>17 Q. Let's back up a minute.</p> <p>18 When you're doing this test, do you</p> <p>19 test both the explants and the controls?</p> <p>20 A. Absolutely.</p> <p>21 Q. And why do you do that?</p> <p>22 A. Because you want to look for</p> <p>23 differences again. First of all, we want to be</p> <p>24 sure that the pristine has it in it, and it did.</p> <p>25 And then we want to see whether or not the</p>	<p>1 Q. Why not?</p> <p>2 A. We didn't think it would have any</p> <p>3 effect on the results.</p> <p>4 Q. Why?</p> <p>5 A. It's not an extracting solvent. It's</p> <p>6 going to dissolve polypropylene, so it's not</p> <p>7 going to have any rapid effect on an extraction.</p> <p>8 Q. Why do you say that?</p> <p>9 A. Well, the polypropylene is solid. It</p> <p>10 doesn't leach out additives quickly unless you</p> <p>11 put it in proper solvent extraction methods. Or</p> <p>12 this case it was simply there, we didn't do an</p> <p>13 extraction method, that's the LCMS, we just</p> <p>14 simply put it in the sample holder and shoot it.</p> <p>15 Q. Have you analyzed the extent to which</p> <p>16 formaldehyde is an oxidant?</p> <p>17 A. No.</p> <p>18 Q. And to the extent formaldehyde is an</p> <p>19 oxidant, you'd expect formalin to be an oxidant,</p> <p>20 wouldn't you?</p> <p>21 A. Right.</p> <p>22 Q. To the extent that formalin is an</p> <p>23 oxidant, it would be appropriate to test the</p> <p>24 polypropylene pristine samples in formalin as a</p> <p>25 part of your PYMS analysis, wouldn't it?</p>
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<p>1 explants have it in it.</p> <p>2 Q. Okay. Did you test the formalin</p> <p>3 controls as a part of the PYMS test?</p> <p>4 (Witness reviewing document.)</p> <p>5 A. It's not shown here. I'm going to</p> <p>6 have to go in the original data. A lot of the</p> <p>7 stuff that was in the original data is not in</p> <p>8 this part.</p> <p>9 MR. ANDERSON: Go to the original</p> <p>10 data.</p> <p>11 MR. THOMAS: Is that all data that's</p> <p>12 been produced to us already?</p> <p>13 A. It's all here, except you've got it on</p> <p>14 dual sided. It's all here. So I have twice as</p> <p>15 much paper.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. While you look for that, I'm going to</p> <p>18 go to the restroom.</p> <p>19 (Pause.)</p> <p>20 A. Repeat the question. I'm sorry. I</p> <p>21 think I've got pretty close.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Did you test the formalin control as a</p> <p>24 part of the PYMS test?</p> <p>25 A. I didn't see it, no.</p>	<p>1 A. It certainly could be done, but we</p> <p>2 didn't do it.</p> <p>3 Q. Because if you found that the</p> <p>4 antioxidants were substantially reduced in the</p> <p>5 formalin control sample, that would impact your</p> <p>6 opinions, wouldn't it?</p> <p>7 A. Yes.</p> <p>8 Q. Why?</p> <p>9 A. Well, then we would imply that the</p> <p>10 formalin extracted the polypropylene additives</p> <p>11 out.</p> <p>12 Q. Have you analyzed at all in connection</p> <p>13 with your work in this case the extent to which</p> <p>14 formalin will extract the antioxidants from the</p> <p>15 polypropylene mesh used in the TVT device?</p> <p>16 A. We didn't do any work with formalin,</p> <p>17 so no.</p> <p>18 Q. So what your findings in the PYMS</p> <p>19 section of the report show is only the pristine</p> <p>20 mesh compared to the explanted mesh treated in</p> <p>21 formalin?</p> <p>22 A. That's correct.</p> <p>23 Q. Now, the next step you take in the</p> <p>24 antioxidant analysis is your LCMS work, correct?</p> <p>25 A. Correct.</p>

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<p>1 Q. That's on Page 84 of your report.</p> <p>2 A. Got it.</p> <p>3 Q. And in this work, you did testing on</p> <p>4 the control samples, didn't you?</p> <p>5 A. Yes.</p> <p>6 Q. And you did test work on the formalin</p> <p>7 control samples, didn't you?</p> <p>8 A. Yes.</p> <p>9 Q. Turn to Page 96, please, of your</p> <p>10 report. Table 19.</p> <p>11 A. 19 starts on Page 95, just so you</p> <p>12 know.</p> <p>13 Q. Thank you. Take your time and look at</p> <p>14 both of them if you want to, both pages.</p> <p>15 A. Okay.</p> <p>16 Q. Let's just talk about it.</p> <p>17 Page 95 begins at Table 19, and it's</p> <p>18 called "Santonox R Relative Quantification," and</p> <p>19 on the left you show sample, on the right you</p> <p>20 show peak area.</p> <p>21 What are you trying to show in this</p> <p>22 table?</p> <p>23 A. The relative amounts of Santonox R in</p> <p>24 the various fibers.</p> <p>25 Q. And Santonox R is one of the</p>	<p>1 A. A lot of -- that's overlay of peaks of</p> <p>2 Santonox R for -- where Santonox R loops at 11.6</p> <p>3 minutes about.</p> <p>4 And extracted ion simply means we know</p> <p>5 we have the 357 ion that shows up, so we tune</p> <p>6 the instrument to see, or to record only the 357</p> <p>7 ion, which is specific to Santonox R, ignoring</p> <p>8 all the other impurities, anything else that</p> <p>9 might also be co-eluting. So it makes the</p> <p>10 method specific.</p> <p>11 Q. So how does the LCMS work?</p> <p>12 A. The liquid is put in from a column</p> <p>13 into the detector and made into a mist, and a</p> <p>14 voltage is applied, and you get ions. The ions</p> <p>15 are put through quadrupoles, which bends them.</p> <p>16 Then it goes through a big tube called a time of</p> <p>17 flight. When it starts going up the tube, a</p> <p>18 clock starts, hits the top, starts coming down,</p> <p>19 and when it reaches the detector at the bottom,</p> <p>20 it hits the other clock, measures literally the</p> <p>21 time between the start and the impact on the</p> <p>22 detector. And then that time is related to the</p> <p>23 mass. It gives you a very accurate mass, which</p> <p>24 is the point of CUTO, giving you very accurate</p> <p>25 mass.</p>
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<p>1 antioxidants in the mesh?</p> <p>2 A. That's correct.</p> <p>3 Q. And the Santonox R is put in the mesh</p> <p>4 to protect against the oxidation that you're</p> <p>5 critical of in this mesh?</p> <p>6 A. Yes.</p> <p>7 Q. And it's your opinion that the</p> <p>8 Santonox R leaches out of the mesh, making it</p> <p>9 more vulnerable to oxidation and environmental</p> <p>10 stress cracking, correct?</p> <p>11 A. Making it, yeah, more susceptible to</p> <p>12 oxidation.</p> <p>13 Q. All right. So on the left you have</p> <p>14 the numbers of your samples, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And on the right you have the peak</p> <p>17 area of Santonox R. What does the peak area</p> <p>18 mean?</p> <p>19 A. It's just we're plotting -- you can</p> <p>20 see the photograph here of the peaks for</p> <p>21 Santonox R right above it, retention time.</p> <p>22 Q. Okay. So what does the chart on Page</p> <p>23 95 represent above this table, the LCMS</p> <p>24 extracted ion chromatograms, and you have all</p> <p>25 the numbers of the samples, what does that mean?</p>	<p>1 Q. What does peak area mean that's</p> <p>2 reported in Table 19?</p> <p>3 A. Just integrate the area under the</p> <p>4 curve that's observed.</p> <p>5 Q. Then you compare the peak area that</p> <p>6 you found for the explant samples against the</p> <p>7 control samples to determine the extent to which</p> <p>8 the Santonox R has been reduced, is that</p> <p>9 correct?</p> <p>10 A. That's correct.</p> <p>11 Q. So, for example, in 13674, the peak</p> <p>12 area is 315,246?</p> <p>13 A. Correct.</p> <p>14 Q. And you compare that to your control</p> <p>15 sample, 3398135, of 2,324,899, that's your</p> <p>16 pristine control sample?</p> <p>17 A. That's pristine control. There's some</p> <p>18 variability there.</p> <p>19 Q. And you'd conclude from that that the</p> <p>20 explant sample has a substantially diminished</p> <p>21 amount of Santonox R, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. The ranges in your control samples are</p> <p>24 as high as 5,418,177, and as low as 2 thousand</p> <p>25 324,899, correct?</p>

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<p>1 MR. ANDERSON: Objection. Million.</p> <p>2 MR. THOMAS: Thank you.</p> <p>3 A. Millions, yes. But you're right.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. If you look at the formalin treated</p> <p>6 control samples on Page 96 at Table 19, the</p> <p>7 formalin treated control samples have less</p> <p>8 Santonox R than the regular control samples,</p> <p>9 don't they?</p> <p>10 A. They do.</p> <p>11 Q. Did you make any analysis to determine</p> <p>12 why?</p> <p>13 A. I would assume that that -- you have</p> <p>14 to assume by the data that that means that</p> <p>15 the -- because it was the same 3405405 was</p> <p>16 analyzed before and after the formalin</p> <p>17 treatment, so formalin treatment extracted some</p> <p>18 of the antioxidant.</p> <p>19 Q. Let's look at that, because the</p> <p>20 formalin treated control sample is 3405405, and</p> <p>21 it says 2,216,989.</p> <p>22 A. Right.</p> <p>23 Q. If you go up to the control sample</p> <p>24 with the same lot number, that means it's the</p> <p>25 same material, just with no formalin, correct?</p>	<p>1 A. That's the only explanation I can</p> <p>2 think of.</p> <p>3 Q. But you didn't study the extent to</p> <p>4 which formalin impacts the antioxidants in the</p> <p>5 mesh as a part of your analysis in this case,</p> <p>6 correct?</p> <p>7 MR. ANDERSON: Objection as to form.</p> <p>8 Go ahead.</p> <p>9 A. No.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. It's correct that you did not?</p> <p>12 A. I did not.</p> <p>13 Q. Thank you.</p> <p>14 Now, if you look at the same table,</p> <p>15 Table 19, you look at lot 3422128.</p> <p>16 A. Where are we now?</p> <p>17 Q. Under "Control Samples," same table,</p> <p>18 Table 19 on Page 96.</p> <p>19 A. Okay.</p> <p>20 Q. You see that there's a control sample</p> <p>21 which is lot number 3422128. Do you see that?</p> <p>22 And a value of 4,550,748. Do you see that?</p> <p>23 A. I see it.</p> <p>24 Q. And then there is another -- a</p> <p>25 duplicate of that same control sample also</p>
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<p>1 A. That's right.</p> <p>2 Q. And the peak area there is 4,012,675,</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. Can't you conclude from that that the</p> <p>6 formalin is extracting the Santonox R from this</p> <p>7 mesh sample?</p> <p>8 A. You can. Not completely, but it is.</p> <p>9 Q. Okay. Is there any other explanation</p> <p>10 for what's going on there?</p> <p>11 A. I don't think so.</p> <p>12 Q. Now, if you look at the other formalin</p> <p>13 control sample, lot number 3422128, it shows a</p> <p>14 peak area of 1,019,604. And if you compare that</p> <p>15 to the same control sample without formalin, the</p> <p>16 number is 4,550,748, correct?</p> <p>17 A. Yes, you're right.</p> <p>18 Q. And it's more than four times the</p> <p>19 amount of Santonox in the pristine sample than</p> <p>20 there is in the formalin sample, correct?</p> <p>21 A. Correct.</p> <p>22 Q. And you have to conclude that the</p> <p>23 reason why there's less in the formalin treated</p> <p>24 sample is because the formalin extracted out</p> <p>25 that Santonox R, correct?</p>	<p>1 tested. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And for that duplicate, that's the</p> <p>4 same piece of mesh, isn't it?</p> <p>5 A. It's a different sample, but it would</p> <p>6 be the same piece of mesh, yes.</p> <p>7 Q. And that's a duplicate of the same</p> <p>8 test with the 4,550,748 test, right?</p> <p>9 A. Right.</p> <p>10 Q. And the value that you get for the</p> <p>11 duplicate sample is 5,418,177, correct?</p> <p>12 A. Correct.</p> <p>13 Q. Do you have any explanation for the</p> <p>14 difference in peak areas between these two, what</p> <p>15 should be duplicate samples?</p> <p>16 A. It should be duplicate samples, but</p> <p>17 it's a different -- it's actually a different</p> <p>18 region in the mesh. So it could be due to the</p> <p>19 fact that the antioxidant is not completely</p> <p>20 evenly distributed in the mesh, so there's</p> <p>21 regions of higher and lower concentration.</p> <p>22 Q. Do you know?</p> <p>23 A. No. I'd have to run a series of</p> <p>24 tests. That's what it's suggestive of.</p> <p>25 Q. Does the fact that the control sample</p>

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<p>1 and the duplicate control sample of the pristine</p> <p>2 mesh tested almost a million DAs apart, does</p> <p>3 that cause you any concern at all?</p> <p>4 A. Well, if it's different it's</p> <p>5 different. I can't control that.</p> <p>6 Q. Okay. Does the fact that the control</p> <p>7 sample lot 3422128, the duplicate, shows a peak</p> <p>8 area of 5,418,177, and the formalin treated</p> <p>9 control sample for the same piece of mesh is</p> <p>10 less than 20 percent of that value, does that</p> <p>11 have any concern -- cause you any concern about</p> <p>12 the opinions you have in the case?</p> <p>13 A. Where are we here? Sorry.</p> <p>14 Q. Okay. We're at Table 19, Page 96.</p> <p>15 You have --</p> <p>16 A. Duplicate.</p> <p>17 Q. You have your duplicate lot for</p> <p>18 3422128, the value is 5,418,177. And the same</p> <p>19 piece of mesh treated with formalin is less than</p> <p>20 20 percent the concentration of Santonox R as</p> <p>21 you found in your pristine sample.</p> <p>22 A. Yes. It looks like formalin is</p> <p>23 extracting it, as we said before.</p> <p>24 Q. Why didn't you note that in your</p> <p>25 report?</p>	<p>1 Q. You had samples in the formalin</p> <p>2 control for how long? 48 hours at 60 degrees</p> <p>3 centigrade?</p> <p>4 A. Yes.</p> <p>5 Q. Did you make any effort to correlate</p> <p>6 the aging by that amount to the samples that are</p> <p>7 contained in Table 19 to determine whether</p> <p>8 they're equivalent?</p> <p>9 A. No.</p> <p>10 Q. It would be appropriate in any</p> <p>11 scientific analysis to make sure that when</p> <p>12 you're comparing formalin exposure, you want</p> <p>13 them to be equal to make sure that they reflect</p> <p>14 accurate values?</p> <p>15 A. Well, the only way to do that, it</p> <p>16 would be rather impossible in this case, it</p> <p>17 would have had to have been implanted in tissue,</p> <p>18 and had to have been implanted and stored in the</p> <p>19 formaldehyde for -- you know, like we'd have to</p> <p>20 take controls. I don't know how we'd put</p> <p>21 controls in tissue. There's all kinds of</p> <p>22 possible requirements to do that technically.</p> <p>23 Q. Is it fair to conclude based on the</p> <p>24 data in your report, at least with respect to</p> <p>25 lot number 3422128, the duplicate sample, and</p>
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<p>1 MR. ANDERSON: Objection.</p> <p>2 A. I did. It's in the table.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. Why didn't you discuss it in your</p> <p>5 report?</p> <p>6 A. Well, there's normally experimental</p> <p>7 error, I can't -- it's possible that this</p> <p>8 million is there because -- instead of 2 million</p> <p>9 because, again, we hit a region of lower</p> <p>10 concentration of the Santonox R, that could be</p> <p>11 part of the reason. Because we see spread in</p> <p>12 the other control values as well.</p> <p>13 Q. Doctor, isn't the best evidence based</p> <p>14 upon the work that you did in this case that the</p> <p>15 formalin is extracting the antioxidants from the</p> <p>16 mesh?</p> <p>17 MR. ANDERSON: Objection as to form.</p> <p>18 Go ahead.</p> <p>19 A. Well, it is extracting some of the</p> <p>20 Santonox R. However, even at the lowest level</p> <p>21 for the majority of these samples, like 13416,</p> <p>22 13418, 13421, there's 67,000 counts to 100,000</p> <p>23 counts, which is 10 to 15 times less than even</p> <p>24 the lowest for formalin control.</p> <p>25 BY MR. THOMAS:</p>	<p>1 the formalin control sample, that the formalin</p> <p>2 is responsible for extracting over 80 percent of</p> <p>3 the Santonox R?</p> <p>4 A. Given the spread on the data, it's</p> <p>5 certainly -- it is suggestive of that. But</p> <p>6 again, it could be 40 percent or 60 percent or</p> <p>7 50 percent because it could be a different</p> <p>8 region of the fiber itself. We have normal</p> <p>9 spread if we run a duplicate like above.</p> <p>10 Q. Let's go above. It's -- even if you</p> <p>11 go to the duplicate above --</p> <p>12 A. That's what -- that's not 80 percent</p> <p>13 difference from the duplicate, it's 20 percent.</p> <p>14 Q. It's almost 50 percent, isn't it?</p> <p>15 A. No. 4,550,000 versus 5,400,000.</p> <p>16 Q. But those are not formalin treated?</p> <p>17 A. No, but that shows the natural</p> <p>18 variability of the mesh.</p> <p>19 Q. But you only -- okay.</p> <p>20 The only data that you have on your</p> <p>21 tests under the LCMS of these explanted meshes</p> <p>22 are contained in this report, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And these are the data upon which you</p> <p>25 rely for your opinions in this case?</p>

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<p>1 A. That's correct.</p> <p>2 Q. And you could have tested other</p> <p>3 regions in the mesh to determine the extent to</p> <p>4 which the antioxidants varied across the mesh,</p> <p>5 correct?</p> <p>6 A. Theoretically. We did a huge amount</p> <p>7 of work to begin with, so it's all a relative --</p> <p>8 what you're capable of doing in the required</p> <p>9 time and all the rest of it, so it's just a</p> <p>10 judgment call.</p> <p>11 Q. The reason why you did testing was to</p> <p>12 have the data points upon which you could</p> <p>13 predicate your opinions?</p> <p>14 A. That's right.</p> <p>15 Q. And these are the only data points</p> <p>16 that you have upon which to predicate your</p> <p>17 opinions?</p> <p>18 A. That's right.</p> <p>19 MR. ANDERSON: Well, objection to</p> <p>20 form.</p> <p>21 A. Not the only, but it's one of.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. For this issue, for the LCMS data?</p> <p>24 A. For Santonox R for the LCMS data, for</p> <p>25 the lauryl thiodipropionate, for example.</p>	<p>1 A. It did not remove at all. It didn't</p> <p>2 remove it to the same levels as seen in the</p> <p>3 explants.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. But it's true to a reasonable degree</p> <p>6 of scientific certainty as reflected by your</p> <p>7 data that the formalin removed more than</p> <p>8 80 percent of the antioxidants as expressed in</p> <p>9 that data?</p> <p>10 MR. ANDERSON: Objection.</p> <p>11 A. I have to look at the numbers.</p> <p>12 (Witness reviewing document.)</p> <p>13 A. The samples -- that's true. And in</p> <p>14 the samples as received, we had like 1, 2 or</p> <p>15 3 percent left, not 80 percent. We only had --</p> <p>16 so it had 97, 98, 99 percent removed in the</p> <p>17 explants we received. Still greater.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. But you don't know how long those</p> <p>20 explants were exposed to formalin, do you?</p> <p>21 A. No, I do not.</p> <p>22 Q. And the length of time those explants</p> <p>23 may have been exposed to formalin would impact</p> <p>24 the extent to which the formalin extracted the</p> <p>25 antioxidants, correct?</p>
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<p>1 Q. As a scientist who works in</p> <p>2 biochemistry and uses this type equipment, does</p> <p>3 the variability in the data in Table 19 on</p> <p>4 Page 96 suggest to you the need to do additional</p> <p>5 testing to confirm the extent to which formalin</p> <p>6 was involved in the extraction of the</p> <p>7 antioxidants?</p> <p>8 A. That would be a good idea, sure.</p> <p>9 Q. Because the data as expressed here is</p> <p>10 not reliable, is it?</p> <p>11 A. Well, that's a relative term. I think</p> <p>12 we certainly got nowhere near the levels seen in</p> <p>13 the explants.</p> <p>14 Q. Is it still your opinion that to a</p> <p>15 reasonable degree of scientific certainty that</p> <p>16 formalin has no impact on the Santonox R in the</p> <p>17 mesh as implanted in a person?</p> <p>18 A. As implanted in a person, I don't --</p> <p>19 Q. Bad question.</p> <p>20 Is it still your opinion to a</p> <p>21 reasonable degree of scientific certainty that</p> <p>22 the formalin had no impact on the measurement of</p> <p>23 antioxidants in the meshes analyzed by you, the</p> <p>24 explants?</p> <p>25 MR. ANDERSON: Objection.</p>	<p>1 A. Presumably.</p> <p>2 Q. Well, absent any testing showing you</p> <p>3 otherwise, that would be the logical conclusion</p> <p>4 from this data, wouldn't it?</p> <p>5 A. Yes.</p> <p>6 MR. THOMAS: Let's eat.</p> <p>7 (Whereupon, a luncheon recess was</p> <p>8 taken at 12:15 p.m.)</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 AFTERNOON SESSION</p> <p>2 1:12 O'CLOCK P.M.</p> <p>3</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. Let's spend a little time with your</p> <p>6 report, Dr. Jordi.</p> <p>7 A. Okay.</p> <p>8 Q. The report in the Lewis case. Let's</p> <p>9 go back to Page 16 again.</p> <p>10 Table 2 on Page 16, it begins on Table</p> <p>11 -- on Page 15, I guess, to be fair.</p> <p>12 A. Yes.</p> <p>13 Q. Table 2 represents what?</p> <p>14 A. Table 2 represents a grid of the tests</p> <p>15 that were run.</p> <p>16 Q. There is a number of sample</p> <p>17 identification numbers beginning with 13400 that</p> <p>18 run to 13421. I assume you did all of those</p> <p>19 tests at once, or about the same time?</p> <p>20 A. About the same time. We received the</p> <p>21 Lewis case a little bit later, so it was run a</p> <p>22 little bit later.</p> <p>23 Q. Is it your practice to number the</p> <p>24 testing that you do in your labs sequentially?</p> <p>25 A. Yes.</p>	<p>1 case has been done since -- the testing work</p> <p>2 itself has been done since September. Does that</p> <p>3 seem about right?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. In Table 2 on Page 15 there's</p> <p>6 identification of the sample, weight, fibers.</p> <p>7 Is that molecular -- what is the weight for</p> <p>8 that? What does that mean?</p> <p>9 A. That was the amount of fibers that</p> <p>10 were able to be extracted. So when you look at</p> <p>11 the picture of the -- on Page 16 at the bottom</p> <p>12 left, those fibers after they were removed from</p> <p>13 tissue were weighed.</p> <p>14 Q. Okay. Is there any weight of a tissue</p> <p>15 that you have?</p> <p>16 A. No. We had no plans for analysis of</p> <p>17 the tissue.</p> <p>18 Q. Did you retain the mesh fibers that</p> <p>19 are in Figure 2?</p> <p>20 A. Well, we would have if there were any</p> <p>21 to maintain. There may be tidbits of a couple</p> <p>22 of them. But with all the testing that was</p> <p>23 done, we were extremely sample constrained.</p> <p>24 Q. How about the tissue samples, did you</p> <p>25 retain any of the tissue samples?</p>
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<p>1 Q. Is there any significance to the</p> <p>2 numbers, other than the time that you do it?</p> <p>3 A. I don't believe so. It's just the</p> <p>4 standard SOP numbering.</p> <p>5 Q. Okay. When did you do the testing for</p> <p>6 13400 to 13421, over what period of time. I</p> <p>7 don't think you'll find it in your report. I've</p> <p>8 got the bills here if that helps.</p> <p>9 MR. ANDERSON: Lab notebooks would</p> <p>10 help, too.</p> <p>11 A. Lab notebooks would probably be</p> <p>12 better.</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. Okay.</p> <p>15 (Witness reviewing documents.)</p> <p>16 A. Looks like about the start was 9/9.</p> <p>17 MR. ANDERSON: Look at your lab</p> <p>18 notebooks instead of saying "about."</p> <p>19 THE WITNESS: I did look at the lab</p> <p>20 notebook there.</p> <p>21 These were all these samples that are</p> <p>22 in that grid, so 9/11, 9/13.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Just from the bills I looked at, it</p> <p>25 appears that the work that has been done in this</p>	<p>1 A. No. We had no further use for the</p> <p>2 tissue.</p> <p>3 Q. Under the 13674, you understand that</p> <p>4 to be the Carolyn Lewis sample?</p> <p>5 A. Yes, I do.</p> <p>6 Q. There's no weight taken there. Do you</p> <p>7 know why?</p> <p>8 A. It was an oversight. It's</p> <p>9 7.62 milligrams. It's in the book.</p> <p>10 Q. Okay. So it's in your lab notebook,</p> <p>11 but never made it to your report?</p> <p>12 A. That was a glitch. It should have</p> <p>13 made it to the report. It didn't make it to the</p> <p>14 report.</p> <p>15 Q. What's the significance of --</p> <p>16 A. It's 7.62 if you want to write it in</p> <p>17 so you've got the exact number.</p> <p>18 Q. What is the significance of that</p> <p>19 number to your analysis?</p> <p>20 A. The milligrams?</p> <p>21 Q. Yes, the weight of the fibers that you</p> <p>22 receive.</p> <p>23 A. It's just a fact of what we got.</p> <p>24 Q. That's what I figured.</p> <p>25 As I look at the sample, explant</p>

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<p>1 sample analysis chart, it lists the tests done</p> <p>2 on each sample, correct?</p> <p>3 A. Correct.</p> <p>4 Q. You didn't do all of the tests on all</p> <p>5 the samples?</p> <p>6 A. Correct.</p> <p>7 Q. Why?</p> <p>8 A. Some cases there just wasn't enough</p> <p>9 sample to do them all. And other cases we --</p> <p>10 like we ran SEM and optical microscopy on all</p> <p>11 the samples. SEM-EDX, once we've seen increased</p> <p>12 oxygen six times, we didn't feel it was</p> <p>13 necessary to run them all. It's already a huge</p> <p>14 report. The volume of work was so great that we</p> <p>15 made choices when we had acquired what we</p> <p>16 considered a significant level of work. Once I</p> <p>17 prove something six times, I don't need to prove</p> <p>18 it seven, eight, nine, ten times. Part of it</p> <p>19 was lack of sample, part of it was we'd run</p> <p>20 enough to be consistent to show the point of the</p> <p>21 various analyses.</p> <p>22 Q. Did the expense of the test have</p> <p>23 anything to do with it, the expense of each of</p> <p>24 the tests?</p> <p>25 A. I'm sure that wasn't the overriding --</p>	<p>1 background in polymer science, this level of</p> <p>2 degradation will have a strong impact on fiber</p> <p>3 mechanical properties, including stiffness,</p> <p>4 elasticity, and resistance to break."</p> <p>5 What level of degradation are you</p> <p>6 describing in that sentence?</p> <p>7 A. We're describing the very obvious</p> <p>8 cracking seen in the SEM photographs.</p> <p>9 Q. Okay. So the level that you're</p> <p>10 describing there relates solely to what you</p> <p>11 observed in the SEM photographs, images?</p> <p>12 A. At this point, yes.</p> <p>13 Q. All right. "Will have a strong impact</p> <p>14 on fiber mechanical properties." What does that</p> <p>15 term mean to you? How much is strong?</p> <p>16 A. Well, we weren't able to run physical</p> <p>17 testing that we normally would run, because we</p> <p>18 didn't have enough material, but we could feel,</p> <p>19 one way is to feel it. The material explanted</p> <p>20 material had a much more rigid feeling to it, I</p> <p>21 guess the best word is rigid, rigid feeling to</p> <p>22 it than the controls.</p> <p>23 Q. Okay.</p> <p>24 A. It was very obvious.</p> <p>25 Q. Is that the only information that you</p>
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<p>1 that wasn't the overriding thing.</p> <p>2 Q. Did you determine which fibers to test</p> <p>3 with which test, or were you directed in that</p> <p>4 regard?</p> <p>5 A. No. We discussed that, and we just</p> <p>6 made a choice of statistical significance.</p> <p>7 Q. Who made that decision?</p> <p>8 A. Well, my son Mark and I.</p> <p>9 Q. Okay. What considerations did you</p> <p>10 have in determining, for example, to do all of</p> <p>11 the OM and SEMs, but only some of the SEM-EDX?</p> <p>12 MR. ANDERSON: Objection. Asked and</p> <p>13 answered.</p> <p>14 Go ahead.</p> <p>15 A. We just didn't feel it was -- we had</p> <p>16 showed the point, and we just thought we had</p> <p>17 done enough work. And we had a huge work</p> <p>18 product to begin with.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Okay. Is there a reason -- strike</p> <p>21 that.</p> <p>22 Let's go to Page 19. Page 19 in the</p> <p>23 middle of the page, it reads this. "It is my</p> <p>24 opinion to a reasonable degree of scientific</p> <p>25 certainty based upon my experience and my</p>	<p>1 have that the level of degradation that you</p> <p>2 observed would have a strong impact on fiber</p> <p>3 mechanical properties?</p> <p>4 A. No. If I looked at the actual flaking</p> <p>5 and the cracking and so on and so forth, that's</p> <p>6 got to have a massive effect. It's a large --</p> <p>7 it covers the entire region of some of the</p> <p>8 fibers.</p> <p>9 Q. Okay. You call it strong, you said</p> <p>10 massive. What does that mean?</p> <p>11 A. Well, the best way I can show it is</p> <p>12 with a picture.</p> <p>13 Q. Okay.</p> <p>14 A. Do you want to see one?</p> <p>15 Q. You've showed them to me, and I've</p> <p>16 seen them.</p> <p>17 In terms of quantifying, placing a</p> <p>18 number on the impact on the mechanical</p> <p>19 properties, you're not able to do that, is that</p> <p>20 fair?</p> <p>21 A. I think you could certainly say it was</p> <p>22 great -- very greatly cracked or moderately</p> <p>23 cracked, something like that in general.</p> <p>24 Putting a number score on it would be difficult,</p> <p>25 yes. But it certainly is not hard to look at a</p>

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<p>1 sample that's grossly cracked and see that it's</p> <p>2 grossly cracked.</p> <p>3 Q. You say that it's "going to have a</p> <p>4 strong impact on fiber mechanical properties,</p> <p>5 including stiffness."</p> <p>6 What impact will this degradation have</p> <p>7 on stiffness?</p> <p>8 A. Cracking, the cracking to me is</p> <p>9 indicative of some -- is a form of degradation,</p> <p>10 at least it's a result of the chemical</p> <p>11 degradation, results in a physical splintering</p> <p>12 that we see. So that when it's largely cracked,</p> <p>13 that also implies that the material underneath</p> <p>14 it is probably cracking, too. And I prove that</p> <p>15 by showing the SEM-EDX and showing the increased</p> <p>16 oxygen levels in the level underneath the</p> <p>17 cracks, that's the next layer that will crack.</p> <p>18 Q. Thank you, Doctor.</p> <p>19 My question is; what level of --</p> <p>20 strike that.</p> <p>21 What amount of stiffness is impacted</p> <p>22 by the level of degradation that you observed in</p> <p>23 the SEM images? What's the -- how can you</p> <p>24 quantify the level of stiffness?</p> <p>25 A. I can just feel it. I'm sorry, I</p>	<p>1 fiber mesh."</p> <p>2 There's nothing in there that I saw</p> <p>3 that suggested that you compared the formalin</p> <p>4 control samples. Do you recall testing the</p> <p>5 formalin control samples in the same way that</p> <p>6 you tested the control samples and the explants?</p> <p>7 A. It's not specifically mentioned, but</p> <p>8 we felt them.</p> <p>9 Q. Okay. And it's your recollection and</p> <p>10 testimony that the explanted samples felt</p> <p>11 stiffer than the control samples?</p> <p>12 A. Most definitely.</p> <p>13 Q. And did you arrive at any conclusions</p> <p>14 about what caused that stiffness?</p> <p>15 A. At the time it was done, we hadn't</p> <p>16 done the other testing, so I had no reason or</p> <p>17 cause. After all the work that's done and</p> <p>18 reported here in this report, the infrared</p> <p>19 showed oxidation, the SEM-EDX shows oxidation,</p> <p>20 the lack of antioxidants would suggest</p> <p>21 susceptibility to oxidation, and so on.</p> <p>22 Q. Okay. The sentence also references</p> <p>23 elasticity. Was the elasticity also something</p> <p>24 that you observed in the handling of the mesh?</p> <p>25 A. Right. If you bent the original --</p>
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<p>1 can't give you a number.</p> <p>2 Q. And just so it's clear, the only thing</p> <p>3 that you have to go on about the stiffness is</p> <p>4 holding the explant in your hands?</p> <p>5 A. In the gloved hands.</p> <p>6 Q. Okay.</p> <p>7 A. And -- yes.</p> <p>8 Q. Comparing it to --</p> <p>9 A. To the control.</p> <p>10 Q. -- the control.</p> <p>11 Did you compare that to the formalin</p> <p>12 control, or just the control?</p> <p>13 A. I think we felt them all.</p> <p>14 Q. I didn't see any reference in your</p> <p>15 report to the formalin control.</p> <p>16 Do you have a -- is it your practice</p> <p>17 when you test the formalin controls to reference</p> <p>18 that in your report?</p> <p>19 A. Reference what in the report?</p> <p>20 Q. The fact that you did it.</p> <p>21 If you go on Page 17, it's where you</p> <p>22 talk about handling it. Page 17 says "It was</p> <p>23 noted during sample preparation that a readily</p> <p>24 apparent difference in fiber stiffness existed</p> <p>25 between the control samples and the explanted</p>	<p>1 the pristine mesh it would come -- pop right</p> <p>2 back to shape. And the other, you had to apply</p> <p>3 more force to get it bent, and it would come</p> <p>4 back and sometimes would stay partially bent, or</p> <p>5 sometimes would crack.</p> <p>6 Q. Is it the handling of the mesh the</p> <p>7 only basis for your opinion that the explanted</p> <p>8 mesh was less elastic than the control?</p> <p>9 A. As a comment here, yes, because that's</p> <p>10 a point where we were running SEM.</p> <p>11 Q. And likewise, with the resistance to</p> <p>12 break, did you observe that in your handling as</p> <p>13 well?</p> <p>14 A. That's right.</p> <p>15 Q. And is it fair to understand that it's</p> <p>16 your handling of the explanted mesh as compared</p> <p>17 to the control mesh that's the basis for your</p> <p>18 opinion that the explanted mesh had less</p> <p>19 resistance to break than the control mesh?</p> <p>20 A. Yes. The control mesh never broke.</p> <p>21 Q. Did you ever investigate any</p> <p>22 alternative potential causes to more stiffness,</p> <p>23 less elasticity, or more resistance to break?</p> <p>24 A. No. We were going after chemical</p> <p>25 analysis of the polypropylene and the</p>

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<p>1 differences, if any.</p> <p>2 Q. Did you ever consider any other</p> <p>3 chemical contributions to increased stiffness --</p> <p>4 strike that.</p> <p>5 Did you ever consider whether formalin</p> <p>6 could contribute to increased stiffness, less</p> <p>7 elasticity, or less resistance to break?</p> <p>8 A. We felt it. The same, it felt the</p> <p>9 same.</p> <p>10 Q. Did you consider that at the time?</p> <p>11 A. If it had been different it would have</p> <p>12 been reported. The fact that it was a formalin</p> <p>13 treated control would be part of the control</p> <p>14 package.</p> <p>15 Q. Well, the formalin treated control</p> <p>16 observations weren't even called out in your</p> <p>17 report, right?</p> <p>18 A. That's right, they weren't.</p> <p>19 Q. Okay. Did you ever consider the</p> <p>20 extent to which formalin and a chemical reaction</p> <p>21 with the proteins on the mesh could lead to an</p> <p>22 increased stiffness, a reduced elasticity, or a</p> <p>23 reduced resistance to break?</p> <p>24 A. No.</p> <p>25 Q. Down in the middle of that paragraph</p>	<p>1 Q. How do you know that's the way it was</p> <p>2 inside the body?</p> <p>3 A. Well, it was in the tissue when it</p> <p>4 came, and we didn't take it out of the tissue</p> <p>5 when we sent it -- when we ran the SEM, so we</p> <p>6 didn't do anything different than it was in the</p> <p>7 body environmentally. We did that on purpose.</p> <p>8 Q. You didn't do anything differently,</p> <p>9 but the doctors did something differently when</p> <p>10 they removed the mesh, didn't they?</p> <p>11 A. Well, they took it out of the body,</p> <p>12 yes.</p> <p>13 Q. What else did they do?</p> <p>14 A. Put it in formalin.</p> <p>15 Q. Okay. Do you know what impact the</p> <p>16 formalin has on the proteins and other -- strike</p> <p>17 that.</p> <p>18 Do you have any knowledge or</p> <p>19 information about what formalin does to the</p> <p>20 materials in the body that surround the mesh?</p> <p>21 MR. ANDERSON: Objection to form.</p> <p>22 A. It will react with the tissue, but it</p> <p>23 will not react -- we ran controls in formalin</p> <p>24 here, and we showed it didn't change the SEM.</p> <p>25 BY MR. THOMAS:</p>
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<p>1 you say "Sharp or protruding surfaces could</p> <p>2 result."</p> <p>3 Do you have an opinion to a reasonable</p> <p>4 degree of scientific certainty that any sharp or</p> <p>5 protruding surfaces resulted from any of these</p> <p>6 pieces of mesh?</p> <p>7 A. Where are we reading here?</p> <p>8 Q. Right in the middle of that paragraph.</p> <p>9 MR. ANDERSON: Page 19.</p> <p>10 A. Oh, 17. All right. Which paragraph?</p> <p>11 MR. ANDERSON: You're on 18. He</p> <p>12 wanted 19. He's going to keep going through</p> <p>13 this paragraph, so here's where he is right now.</p> <p>14 A. "Sharp protruding..."</p> <p>15 (Witness reviewing document.)</p> <p>16 A. Okay. Question again, please?</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Do you have an opinion to a reasonable</p> <p>19 degree of scientific certainty that any sharp or</p> <p>20 protruding surfaces resulted on any of the mesh</p> <p>21 explants that you reviewed in vivo?</p> <p>22 MR. ANDERSON: Objection to form.</p> <p>23 A. We saw the sharp edges in the SEM</p> <p>24 photos.</p> <p>25 BY MR. THOMAS:</p>	<p>1 Q. But the ones you ran in formalin</p> <p>2 didn't have any tissue on them.</p> <p>3 MR. ANDERSON: Wait a minute, Dave, in</p> <p>4 fairness let him finish his answer.</p> <p>5 MR. THOMAS: You're right.</p> <p>6 A. We ran formalin treated controls here</p> <p>7 to see if it would do anything obvious to the</p> <p>8 pristine. It did not.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. But the formalin controls that you ran</p> <p>11 didn't have any tissue on them.</p> <p>12 A. That's correct. So what?</p> <p>13 Q. And my question is whether you know</p> <p>14 whether formalin will react with the tissue on</p> <p>15 the mesh so as to impact the appearance in the</p> <p>16 SEM images. Do you know that?</p> <p>17 A. Absolutely not. It will react with</p> <p>18 the tissue, absolutely. It's irrelevant. It's</p> <p>19 not going to react with the mesh. It will</p> <p>20 react -- not react with the mesh in the tissue,</p> <p>21 it will react with the tissue which we removed,</p> <p>22 so it's no longer there when we did the testing.</p> <p>23 Q. Is it your testimony there was no --</p> <p>24 A. There was tissue on when the SEMs were</p> <p>25 run. We didn't want that removed because didn't</p>

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<p>1 want to in any way disturb the mesh in any way  2 that we could possibly avoid, so we tried our  3 very best not to cause anything, any changes.  4 So we ran the SEMs in the tissue, which we could  5 do.  6 Q. What is your area of expertise that  7 allows you to give the opinion that "Prolene  8 mesh in the TVT products degrades, cracks, and  9 releases polypropylene particulates into the  10 surrounding tissue after implantation, causing  11 an increased inflammatory response"? Are you  12 trained to give that opinion?  13 A. I certainly am. I'm a polymer  14 chemist, a biochemist, and we actually saw the  15 shards, we saw how easily the shards came off,  16 and then we actually took an infrared of it to  17 show that they were polypropylene. So we  18 actually did it and we saw it.  19 Q. That's not -- that's a good answer. I  20 should have asked a better question.  21 What's your training, education, and  22 experience that allows you to give the opinion  23 that those pieces that you claim break off  24 caused an increased inflammatory response?  25 A. What's my basis?</p>	<p>1 A. That was well understood in that we  2 had very little response. Because in that case,  3 unlike this case, we had a polymer in polylactic  4 and polyglycolic acid which degraded to lactic  5 acid and glycolic acid, both of which are normal  6 body chemicals that don't cause a tissue  7 response of any consequence.  8 Q. Was it your job to determine the  9 extent to which the jaw implant would integrate  10 into the tissue?  11 A. To observe it.  12 Q. Was it your job to determine the  13 adequacy of the design of the jaw implant to be  14 accepted by the tissue?  15 A. Well, we worked as a team. There was  16 a number of us.  17 Q. But there were other people whose  18 primary responsibility was to determine the  19 extent to which the implant was compatible with  20 existing tissue, wasn't it?  21 A. That work had been done prior, it had  22 been shown to be compatible.  23 Q. But that was not your job?  24 A. No.  25 Q. Somebody else did that work? Another</p>
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<p>1 Q. Yes. What's your training?  2 A. I'm a biochemist.  3 Q. As a part -- have you analyzed the  4 effect of polymer degradation in humans prior to  5 this litigation?  6 A. I worked on bio-implantable polymers  7 when I was in the Army at Walter Reed Army  8 Medical Center, polylactic acid, polyglycolic  9 acid copolymers.  10 Q. Was your work there --  11 MR. ANDERSON: He's not finished.  12 Go ahead.  13 A. We were replacing parts of jaws in  14 animals with a goal of being able to replace a  15 blown off jaw on a soldier, put a piece of  16 implantable material in the jaw, and then we  17 wanted the tissue to grow into it, so we put  18 things in the PLA-PG polymer so tissue would  19 tend to grow in, and ultimately the jaw would be  20 replaced with new jaw, and it worked fairly  21 well.  22 BY MR. THOMAS:  23 Q. Was it your job to determine the  24 extent to which the implant would be accepted by  25 existing tissue?</p>	<p>1 expertise was required to make that finding,  2 correct?  3 A. Right.  4 Q. And so --  5 A. But it's not unreasonable to observe  6 polypropylene shards coming off, which are  7 little knives. They're going to cut the tissue  8 when they come off in it. You can see it under  9 microscope, and that's going to cause bleeding  10 and an inflammatory response.  11 Q. How big are these shards you're  12 talking about?  13 A. Well, let's go look at a picture.  14 We've got a scale on it. They vary.  15 Q. How big is that one? What page are  16 you on?  17 A. 69.  18 Q. How big is it?  19 MR. ANDERSON: Which piece? There's  20 pieces all over the place.  21 MR. THOMAS: The piece he has  22 highlighted right there.  23 MR. ANDERSON: Okay.  24 A. Well, the mesh itself is, what, 70,  25 80 microns, so it's got to be -- this is a good</p>



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<p>1 size piece, so it's probably 20 microns,  2 10 microns, 20 microns, depends on the piece.  3 BY MR. THOMAS:  4 Q. And it's your opinion that that cuts  5 tissue?  6 A. Absolutely. If it's got sharp edges  7 like this and you're moving around and  8 exercising, it's got to drive it into  9 whatever --  10 Q. What have you done to study the extent  11 to which a shard as depicted on the Page 69 is  12 going to have any impact at all in terms of  13 inflammatory response in a human?  14 A. I leave that to the doctors, the  15 surgeons, and so on, and the doctors. I'm not  16 a -- I'm a biochemist and a polymer chemist.  17 Q. Right. So the extent to which any of  18 these edges that you've described, cracks that  19 you've described, or platelets or shards that  20 you've described are going to have any health  21 impact on any patient is for somebody else to  22 comment on, is that fair?  23 A. The doctors have to do that, yes.  24 Q. Thank you.  25 Let's go to Page 42 of your report,</p>	<p>1 you draw a circle around what you've described  2 as the polypropylene.  3 MR. ANDERSON: On his copy? Do you  4 want to put it on -- let's put it on the record  5 copy.  6 MR. THOMAS: That's what I thought he  7 was looking at. I'm sorry.  8 A. It would be the same page.  9 BY MR. THOMAS:  10 Q. So we're on Page 42 of Exhibit 1.  11 A. Yes.  12 MR. ANDERSON: You're going to write  13 on this.  14 BY MR. THOMAS:  15 Q. So why don't you draw a circle around,  16 if you don't mind, those areas --  17 A. Circle?  18 MR. ANDERSON: Listen to him.  19 BY MR. THOMAS:  20 Q. Outline the area that you believe is  21 polypropylene.  22 A. (Witness complies).  23 I'm having a hard time writing  24 exactly, but you give my drift.  25 BY MR. THOMAS:</p>
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<p>1 please.  2 A. Got it.  3 Q. I'm interested in the figure that's on  4 the lower half of the page. I guess it's Figure  5 48.  6 Based on your work in this case, what  7 does Figure 48 show?  8 A. It shows a large -- this is atypical.  9 It shows a large longitudinal crack in the  10 underlying polypropylene coated by what appears  11 to be tissue.  12 Q. Okay. Which parts -- I look at that  13 and I think of bark on a tree. And there's  14 areas on either side, and then an interior that  15 I would think of as exposed wood on a tree and  16 the rest would be the bark, and I'm trying to  17 use it as kind of a descriptive thing.  18 Is the area surrounding the interior  19 portion -- that's not going to make any sense at  20 all on the record, I understand that. Are we  21 talking about the same thing? Is that the  22 tissue that's surrounding it?  23 A. Yes. This would be the polypropylene  24 in here (indicating).  25 Q. Let me give you a red pen. Why don't</p>	<p>1 Q. Doesn't have to be exact.  2 A. Looks like a crack there.  3 Q. Okay.  4 A. Something on that order.  5 Q. And so thank you for doing that.  6 You've drawn in red the area inside of  7 which is the polypropylene. Does the area  8 outside of that represent tissue or protein?  9 A. I believe so.  10 Q. Okay.  11 A. It doesn't match -- you can see when  12 polypropylene cracks it gives these sharp sides  13 and jagged edges, whereas this is more -- tissue  14 is more nebulous.  15 Q. What is it about the polypropylene  16 structure that causes it to crack in the manner  17 you just described?  18 MR. ANDERSON: Objection to form.  19 Go ahead.  20 A. It's developed brittleness from lack  21 of antioxidants and oxidation and/or stress  22 cracking. The two work together in any given  23 sample.  24 BY MR. THOMAS:  25 Q. Will degradation alter the melting</p>

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<p>1 point of polypropylene?</p> <p>2 A. Yes.</p> <p>3 Q. Will degradation always alter the</p> <p>4 melting point of polypropylene?</p> <p>5 A. I think it depends on the severity of</p> <p>6 the oxidation, the degradation.</p> <p>7 Q. How much degradation or oxidation is</p> <p>8 required to alter the melting point of</p> <p>9 polypropylene?</p> <p>10 A. Well, a lot of things affect the</p> <p>11 melting point of polypropylene. I'll show you.</p> <p>12 This is again from one of the books in my --</p> <p>13 Turi, on thermal methods. Here's a chart, it</p> <p>14 details polypropylene, and I've got melt points</p> <p>15 all the way from 106 to 114 degrees to</p> <p>16 176 degrees, depending on the percent</p> <p>17 crystallinity. Percent crystallinity affects</p> <p>18 the melt point.</p> <p>19 Q. Did you determine the melt point of</p> <p>20 the mesh that you analyzed in this project?</p> <p>21 A. Yes.</p> <p>22 Q. What did you determine the melt point</p> <p>23 to be, do you remember?</p> <p>24 A. I'd have to go to the table. There</p> <p>25 were different values.</p>	<p>1 BY MR. THOMAS:</p> <p>2 Q. We've got too many papers working</p> <p>3 here. I apologize.</p> <p>4 What is a plasticizer?</p> <p>5 A. It's generally a low molecular weight</p> <p>6 material that's put inside of a plastic to make</p> <p>7 it more flexible.</p> <p>8 Q. Do you agree that fat and body tissue</p> <p>9 will be a plasticizer on polypropylene?</p> <p>10 A. Yes, not on, though, in. Only in. It</p> <p>11 has to get in.</p> <p>12 Q. What does that mean when the fat and</p> <p>13 body tissue soften the polypropylene?</p> <p>14 A. It just becomes softer, because --</p> <p>15 that's connected with the environmental stress</p> <p>16 cracking, that's going to get into the polymer</p> <p>17 and start swelling the chains.</p> <p>18 Q. Are you familiar with the concept</p> <p>19 known as toughness?</p> <p>20 A. Yeah.</p> <p>21 Q. What is toughness?</p> <p>22 A. It's resistance to wear.</p> <p>23 Q. Is implanted mesh tougher than</p> <p>24 pristine mesh?</p> <p>25 A. Not seen the measurements, so I don't</p>
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<p>1 Q. We'll get to that.</p> <p>2 You use a reference point in your</p> <p>3 report of 175.</p> <p>4 A. That's for a typically crystalline</p> <p>5 polypropylene material.</p> <p>6 Q. The actual melting point of the</p> <p>7 polypropylene you analyzed was lower than that?</p> <p>8 A. It was all lower, which tells me it</p> <p>9 was -- after the manufacturing process it was</p> <p>10 like 165, I think, roughly, and then it went</p> <p>11 down from there.</p> <p>12 Q. Okay.</p> <p>13 A. It varies as a function of molecular</p> <p>14 weight, it varies as a function of</p> <p>15 crystallinity.</p> <p>16 Do you want to keep this together? Do</p> <p>17 you know where the start is for this? This is</p> <p>18 mine.</p> <p>19 MR. ANDERSON: I think he flipped it</p> <p>20 over, so we'll just have to figure it out.</p> <p>21 THE WITNESS: I don't want to get us</p> <p>22 all mixed up.</p> <p>23 MR. ANDERSON: There we go.</p> <p>24 A. We've got it ready if we need it for</p> <p>25 something else.</p>	<p>1 know.</p> <p>2 Q. Have you ever analyzed the question of</p> <p>3 whether implanted mesh is tougher than pristine</p> <p>4 mesh?</p> <p>5 A. No.</p> <p>6 Q. What does it mean if implanted mesh is</p> <p>7 tougher than pristine mesh?</p> <p>8 A. Well, it just means it might be</p> <p>9 tougher in the sense of, I would use the term --</p> <p>10 I'm more like using the term rigid in this case,</p> <p>11 that would probably also be considered as part</p> <p>12 of this tougher thing. But it also would make</p> <p>13 it -- if it's more rigid, it's going to make it</p> <p>14 more difficult to move in the body, and the</p> <p>15 patient will have more difficulty doing exercise</p> <p>16 and the like with that type of thing.</p> <p>17 Q. If it's tougher --</p> <p>18 A. It's tougher --</p> <p>19 Q. -- it's less resistant to be brittle</p> <p>20 and break, isn't it?</p> <p>21 A. Well, we also -- yes, but we also have</p> <p>22 to consider based on our -- again, back to our</p> <p>23 SEM photographs, we also have to consider there</p> <p>24 appears to be two distinctive layers here,</p> <p>25 there's a surface layer which is cracking and</p>

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<p>1 there's an underlying layer which is -- has not  2 yet cracked. So the bulk material could be  3 tougher, while the surface layer is more  4 brittle, at the same time.  5 Q. Okay.  6 A. So I don't know what to make of your  7 term because you're lumping it in the bulk, you  8 know, as the entire fiber. And I'm looking at  9 two fibers, the surface region and then the  10 underlying region, which is not cracked yet.  11 Q. Just to be clear, they are both parts  12 of the same fiber, aren't they?  13 A. They almost look like two separate  14 fibers.  15 Q. Okay.  16 A. And there's publications which  17 indicate the same.  18 Q. Did you cite those papers in your  19 report?  20 A. Yes.  21 Q. Which papers are we talking about now?  22 A. Well, let's see if I can find it for  23 you quick. You'll have to bear with me while I  24 find it.  25 (Witness reviewing document.)</p>	<p>1 suggest that the stress cracking phenomenon is  2 oriented along the extrusion lines?  3 A. No. It doesn't say one way or the  4 other. It just says "stress cracking phenomenon  5 in oriented." She's just discussing oriented  6 polypropylene. She doesn't say where the cracks  7 are.  8 Q. Okay. I understand. Go ahead.  9 A. "Has been explained by their  10 pronounced skin to core structure. This  11 bi-component structure is created by the  12 differential cooling rates between the external  13 and internal layers of the monofilaments." When  14 it comes out of the dye, the surface cools  15 faster than the inner core. The faster cooling  16 outer surface is going to be less crystalline  17 than the inner core which stays warm longer, has  18 more time to form crystals as it's cooling. So  19 you wind up with two structure types in the  20 filament when you're done.  21 Q. Are you suggesting by this testimony,  22 Doctor, that it's only the outside of the  23 polypropylene mesh that's degrading, and the  24 inside is fine?  25 MR. ANDERSON: Objection.</p>
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<p>1 A. I've got it, I think. This is paper  2 ASIO journal, 1998, Page 199, Mary Celine,  3 "Comparison of in vivo behavior of  4 polyvinylidene fluoride and polypropylene  5 sutures used in vascular surgery."  6 She's discussing stress cracking at  7 this point. She says "The reason for stress  8 cracking phenomenon in oriented polypropylene  9 monofilaments has been explained by their  10 pronounced skin/core structure." Those are two  11 phases I'm talking about.  12 Q. Let me stop you there.  13 What is oriented polypropylene  14 monofilaments? What does that mean?  15 A. It means it's gone through the dye and  16 it's oriented longitudinally. We can see those  17 lines where it's been pulled through the dye, or  18 pushed.  19 Q. Does that suggest a stress cracking  20 phenomenon occurs through the extrusion lines?  21 A. Well, her purpose here is not to talk  22 about that at the moment. It's talking about  23 the bi-component structure.  24 Q. I understand that.  25 But as you read that, does that</p>	<p>1 Go ahead.  2 A. I'm not suggesting any such thing.  3 I'm suggesting that the outer core is  4 chemically less crystalline, and hence more  5 stress cracking susceptible, than the inner  6 part. The inner part would still be susceptible  7 over time depending on the degree of  8 implantation in the body to oxidation.  9 We have two different things going on  10 at the same time, two layers. There are  11 actually two different kinds of polypropylene,  12 although that wasn't the intent in the  13 manufacture I'm sure, but that's what you wind  14 up with.  15 BY MR. THOMAS:  16 Q. Each of which will require a breakdown  17 in the polymer to degrade as described?  18 A. Each of which --  19 Q. Sorry.  20 Each of which would require a  21 breakdown in the polypropylene in order to  22 degrade as described?  23 A. Right. And the surface layer being  24 less crystalline would also bleed out its  25 antioxidants faster, it's more amorphous, and so</p>

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<p>1 it's going to tend to degrade first. And that's</p> <p>2 what we invariably see in the SEMs, we see a</p> <p>3 surface cracking and removal.</p> <p>4 Q. In your analysis of these explanted</p> <p>5 meshes, did you ever see a crack all the way</p> <p>6 through the mesh?</p> <p>7 A. I don't think we did. But I've read</p> <p>8 about them in the literature, I just never saw</p> <p>9 one in the 23 samples we ran, 24 with Batiste.</p> <p>10 Q. Do you have any recollection -- strike</p> <p>11 that.</p> <p>12 Do you know the greatest crack that</p> <p>13 you observed in any of the meshes that you</p> <p>14 reviewed?</p> <p>15 A. Do I --</p> <p>16 Q. Are you able to point to me the</p> <p>17 biggest crack on any of the meshes and quantify</p> <p>18 for me how much that crack is compared to the</p> <p>19 rest of the mesh? I don't want -- if you don't</p> <p>20 know it, I don't want you to go look.</p> <p>21 A. There is a range, certainly.</p> <p>22 Q. Can you quantify in measurement?</p> <p>23 A. Standing here without looking at the</p> <p>24 pictures, no.</p> <p>25 Q. Is there anything about the pictures</p>	<p>1 temperature was raised in a heat cycle which is</p> <p>2 listed in Table 4, heating conditions. First</p> <p>3 heat we went from minus 90C to 200C at 10</p> <p>4 degrees C per minute. Then we cooled from 200</p> <p>5 back to minus 90 at 10 degrees C per minute.</p> <p>6 And then we reheated a second heat from minus 90</p> <p>7 to 210 degrees C per minute.</p> <p>8 The first heating cycle looks at the</p> <p>9 form of the material as received. And then the</p> <p>10 second heating cycle looks at the innate</p> <p>11 material itself, heat history of the material</p> <p>12 erased, so all the samples then go to what's</p> <p>13 called a common heat history. They may not all</p> <p>14 have a common heat history in the first heat</p> <p>15 cycle, but, of course, that's the way they</p> <p>16 actually are in the body so that's the most</p> <p>17 important one to look at is the Delta H and the</p> <p>18 melting point, the first melting point in the</p> <p>19 first Delta H.</p> <p>20 Q. In Table 5, did you provide data for</p> <p>21 all of your explant samples?</p> <p>22 A. Let's see. No, there's 15 samples, we</p> <p>23 had 23. So there were seven that weren't run.</p> <p>24 Q. Is there a reason why you didn't test</p> <p>25 them all?</p>
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<p>1 that allows you -- strike that.</p> <p>2 Did you measure the cracks as a part</p> <p>3 of your work in this case?</p> <p>4 A. No. Actually the entire surface was</p> <p>5 cracked in many cases, so the entire surface</p> <p>6 would simply come off.</p> <p>7 Q. Let's go to Page 60 of your report,</p> <p>8 please.</p> <p>9 This is the differential scanning</p> <p>10 calorimetry?</p> <p>11 A. Calorimetry.</p> <p>12 Q. Calorimetry. Thank you. We've talked</p> <p>13 around this a lot today.</p> <p>14 Would you tell me exactly what this is</p> <p>15 and what it measures?</p> <p>16 A. DSC is a technique that -- where you</p> <p>17 put energy into a pan, against a standard pan in</p> <p>18 the other side, and you measure the rate of heat</p> <p>19 absorption or dissipation of a sample as the</p> <p>20 temperature rises or drops. You can both heat</p> <p>21 and cool it.</p> <p>22 Q. Okay. And tell me how you set out to</p> <p>23 measure those things with the DSC methodology?</p> <p>24 A. Well, a portion of the sample was put</p> <p>25 into the tube, into the sample pan, and then the</p>	<p>1 MR. ANDERSON: Objection. Asked and</p> <p>2 answered.</p> <p>3 Go ahead.</p> <p>4 A. I remember we didn't need to run all</p> <p>5 the samples to show the trends, number one.</p> <p>6 And number two, some of these cases</p> <p>7 there simply wasn't enough material to run.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. Let's go to Page 66, please, the FTIR</p> <p>10 microscopy. Let's talk about what FTIR</p> <p>11 microscopy is. Tell me what that is, please.</p> <p>12 A. An FTIR microscope, FTIR instrument,</p> <p>13 you radiate the sample with infrared radiation.</p> <p>14 Each type of chemical bond in a molecule will</p> <p>15 absorb infrared radiation at a different wave</p> <p>16 length. So when you run across a range of wave</p> <p>17 lengths, typically from 4,000 reciprocal</p> <p>18 centimeters to 5 or 600 reciprocal centimeters</p> <p>19 you get a picture, a literal picture, to a</p> <p>20 chemist anyway, a picture of the bonds in the</p> <p>21 molecule that you're looking at.</p> <p>22 Q. Now, when you do FTIR analysis, do you</p> <p>23 generally have a reference against which to</p> <p>24 measure what you find to match up?</p> <p>25 A. That's always run with references. We</p>

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<p>1 always run -- to make sure the instrument is</p> <p>2 running fine, usually a polystyrene standard is</p> <p>3 run to make sure all the bands come out where</p> <p>4 they should come out. And then CO2 is removed</p> <p>5 with a nitrogen purge so you don't have an</p> <p>6 artificial CO2 peak. That's SOP. That's all in</p> <p>7 the SOP.</p> <p>8 Q. Okay. Do you then have a</p> <p>9 polypropylene reference point against which to</p> <p>10 compare your findings that you shoot here to see</p> <p>11 how they match up?</p> <p>12 A. Well, we have polystyrene --</p> <p>13 polypropylene reference spectra, so -- and we</p> <p>14 run the standard polypropylene mesh, which is,</p> <p>15 in fact, pure polypropylene. So we compare</p> <p>16 that.</p> <p>17 Number one, the polystyrene shows the</p> <p>18 instrument is behaving good, up to standard, and</p> <p>19 then the polypropylene is run, it's compared to</p> <p>20 a known polypropylene spectrum. So if we were</p> <p>21 to run the mesh and the peaks looked funny we</p> <p>22 would have caught that. Although that's never</p> <p>23 happened, because if the polystyrene standard</p> <p>24 comes out right, it's telling you the machine is</p> <p>25 working normally.</p>	<p>1 don't match I know I've got a problem, and I</p> <p>2 stop and fix it, we don't continue.</p> <p>3 Q. Believe it or not, I think we're</p> <p>4 saying the same thing.</p> <p>5 A. Hopefully so.</p> <p>6 Q. I don't use the same words you do.</p> <p>7 A. If you'd like to see the standard,</p> <p>8 I've got in my book over there. I'll be glad to</p> <p>9 show it to you.</p> <p>10 Q. Which standard did you use, the</p> <p>11 Sadtler?</p> <p>12 A. The Sadtler.</p> <p>13 Q. I don't need to see it.</p> <p>14 Do you call that a standard? What's</p> <p>15 the technical term for that?</p> <p>16 A. No, I call it a check. It is a type</p> <p>17 of -- it's part of our SOP. But the standard is</p> <p>18 the polystyrene, it's always run.</p> <p>19 Q. The Sadtler reference that you talked</p> <p>20 about --</p> <p>21 A. Is polypropylene.</p> <p>22 Q. And it would be the same sort of</p> <p>23 spectrum that appears on Page 67 of your report?</p> <p>24 A. Exactly.</p> <p>25 Q. And you would measure the Sadtler</p>
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<p>1 But even if it did for some crazy</p> <p>2 reason, between the time we ran the standard and</p> <p>3 the time we ran the polypropylene, we'd</p> <p>4 immediately flag it because we have</p> <p>5 polypropylene standard spectra around.</p> <p>6 Q. Is the goal of running the FTIR to</p> <p>7 determine the extent to which what you're</p> <p>8 testing matches up against what you're looking</p> <p>9 for; that is, particularly here that you're</p> <p>10 testing the explanted mesh to determine the</p> <p>11 extent to which it's consistent with the</p> <p>12 polypropylene that's supposed to be in the mesh?</p> <p>13 A. Yes.</p> <p>14 Q. And there are standards against which</p> <p>15 you measure what your findings are?</p> <p>16 A. Correct.</p> <p>17 Q. And there will be a standard -- there</p> <p>18 are a number of different companies that make</p> <p>19 standard polypropylene spectra against which you</p> <p>20 could measure your findings?</p> <p>21 A. Yes. But we don't need that because</p> <p>22 we use the spectra, or the known spectra from</p> <p>23 like Sadtler Library of spectra, I will simply</p> <p>24 look up what I'm getting versus a known</p> <p>25 standard, and those two have to match. If they</p>	<p>1 standard for polypropylene against what you find</p> <p>2 to see if it matches what you find?</p> <p>3 A. That's right. In other words, for</p> <p>4 isotactic polypropylene, which is what Prolene</p> <p>5 is, we have 841, 973, 997, and 1166 bands, those</p> <p>6 are the isotactic bands. It's a fingerprint, we</p> <p>7 call it, of polypropylene, and particularly of</p> <p>8 isotactic polypropylene.</p> <p>9 Q. Do you know of any polypropylene</p> <p>10 standards that have a spectra for oxidized</p> <p>11 polypropylene?</p> <p>12 MR. ANDERSON: Objection.</p> <p>13 Go ahead.</p> <p>14 A. I've seen them.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Did you attempt to -- where did you</p> <p>17 see them?</p> <p>18 A. The Sadtler Library. There's a</p> <p>19 chapter on polypropylenes, and some of them are</p> <p>20 oxidized and some aren't.</p> <p>21 Q. Okay. Have you read about FTIR</p> <p>22 spectra for oxidized polypropylene?</p> <p>23 A. I've just seen them in the Sadtler</p> <p>24 Library.</p> <p>25 Q. Did you consider utilizing spectra for</p>

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<p>1 oxidized polypropylene when you conducted your</p> <p>2 FTIR analysis in Lewis and Batiste?</p> <p>3 A. No. I used more of the literature,</p> <p>4 the Clavés, the Ostergards, and Wood, the</p> <p>5 current Wood paper and others. They all run</p> <p>6 infrared of polypropylene.</p> <p>7 Q. Why didn't you use the standards which</p> <p>8 have oxidized polypropylene against which to</p> <p>9 measure your findings?</p> <p>10 A. Well, those were -- those were bulk</p> <p>11 polypropylenes, this is fiber. So I didn't</p> <p>12 really have any fiber standard spectra to use</p> <p>13 anyway. So I guess I could have used them,</p> <p>14 wouldn't have hurt, wouldn't have made any</p> <p>15 difference, I don't think.</p> <p>16 Q. Why not?</p> <p>17 A. Because I already had them from the</p> <p>18 other literature.</p> <p>19 Q. But you are measuring something</p> <p>20 different with oxidized polypropylene than you</p> <p>21 are with regular polypropylene by your own</p> <p>22 definition, correct?</p> <p>23 A. Right. As shown in the literature I</p> <p>24 already have.</p> <p>25 Q. The literature you're talking about is</p>	<p>1 correct?</p> <p>2 MR. ANDERSON: Objection. Form.</p> <p>3 Go ahead.</p> <p>4 A. I certainly could have used those. I</p> <p>5 don't see it makes any difference. I'm using</p> <p>6 published literature, recent published</p> <p>7 literature here, so I feel very safe. I mean I</p> <p>8 could have used the Sadtler Library, sure.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. Well, if the Sadtler Library gave you</p> <p>11 a different result, you'd be concerned, wouldn't</p> <p>12 you?</p> <p>13 A. But it's not going to. I'm confident</p> <p>14 sitting here it's not going to give me a</p> <p>15 different result. I'll go get the spectra and</p> <p>16 show you, glad to.</p> <p>17 Q. The range of absorption regions</p> <p>18 identified by you as being indicative of</p> <p>19 oxidation are 1730 to 1680, is that correct?</p> <p>20 A. Right. That would include acids</p> <p>21 around 1700, ketones around 16 -- 1710, 15, and</p> <p>22 then aldehydes around 1730, esters around 1740.</p> <p>23 Q. Do you have anything -- did you find</p> <p>24 anything in your FTIR analysis of evidence of</p> <p>25 oxidation in the range of 1730 to 1680?</p>
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<p>1 Clavé?</p> <p>2 A. Yeah, Clavé and there's others. Wood</p> <p>3 is another one, that's 2013.</p> <p>4 Q. Is that contained in your report?</p> <p>5 MR. ANDERSON: Yes.</p> <p>6 A. I think so.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. May I see that, please?</p> <p>9 A. Sure. If you want, I'll make you a</p> <p>10 copy.</p> <p>11 Q. We'll take care of that later.</p> <p>12 Just for the record, this is the</p> <p>13 Journal of Material Science, 2013, 24:1113-1122,</p> <p>14 A.J. Wood, "Materials Characterization,</p> <p>15 Historical Analysis of Explanted" -- I've seen</p> <p>16 this before -- "Polypropylene PTFE and PET</p> <p>17 Hernia Meshes."</p> <p>18 You're referring to the FTIR spectra</p> <p>19 on Page 1117, is that correct?</p> <p>20 A. Yes, sir.</p> <p>21 Q. And 1118?</p> <p>22 A. Yes, that's part of the paper.</p> <p>23 Q. So you relied on this rather than the</p> <p>24 standards in Sadtler or others that may have</p> <p>25 FTIR spectra for oxidized polypropylene,</p>	<p>1 A. It was covered up by the protein that</p> <p>2 was in the coating, or part of -- I guess you</p> <p>3 could say coating the fiber pieces.</p> <p>4 Q. So is the answer no?</p> <p>5 A. The answer is no.</p> <p>6 Q. Now, when you run these FTIR samples,</p> <p>7 you set the machine, the machine reads it, and</p> <p>8 then the machine is what identifies those areas</p> <p>9 that are significant and calls them out with</p> <p>10 numbers, is that right?</p> <p>11 A. The frequencies of each band, yes, the</p> <p>12 machine calls out, yes.</p> <p>13 Q. The frequencies of each band?</p> <p>14 A. Yes.</p> <p>15 Q. So the numbers that appear, for</p> <p>16 example, on Page 69, along with the spectra</p> <p>17 there, those numbers are placed there by the</p> <p>18 machine based upon your calibration of the</p> <p>19 machine about what's significant. Is that fair?</p> <p>20 A. Well, it's simply identifying -- the</p> <p>21 machine identifies the peaks and labels the</p> <p>22 numbers. I have to interpret what it means.</p> <p>23 We also have -- the computer these</p> <p>24 days can make estimates and look for matches,</p> <p>25 too.</p>

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<p>1 Q. Okay. On Page 69, you've identified</p> <p>2 this area at 1757 as being significant, is that</p> <p>3 right?</p> <p>4 A. Right. There's also another region</p> <p>5 I'd like to mention, it's a little bit subtle,</p> <p>6 is that shoulder that's at the base of the 1656</p> <p>7 peak, towards the left side of it, that would be</p> <p>8 the 1740. The machine didn't pull it out</p> <p>9 because there's not a baseline, not a valley in</p> <p>10 there for it to see. The machine requires a</p> <p>11 valley to see. But the human eye can see it.</p> <p>12 Q. I see.</p> <p>13 So that shoulder is something --</p> <p>14 A. That's the 1740.</p> <p>15 Q. -- that the machine didn't find, but</p> <p>16 you find?</p> <p>17 A. Right. The human brain can still be a</p> <p>18 machine occasionally.</p> <p>19 Q. I see.</p> <p>20 A. And if I had taken this sample and</p> <p>21 treated it with sodium hypochlorite, for</p> <p>22 example, then we would have gotten rid of the</p> <p>23 1656 and the 1541 bands, which are the protein</p> <p>24 bands, because we have destroyed the protein or</p> <p>25 the biofilm that was part of the particle or</p>	<p>1 liquid or gas, in the case of polypropylene, and</p> <p>2 then as they monitor units, fuse together, the</p> <p>3 chains become longer and longer, and then you</p> <p>4 have eventually a polymer -- generally the start</p> <p>5 of what we call a polymers around, it's a bit of</p> <p>6 a range, but we generally consider anything</p> <p>7 above 2000-ish molecular weight of daltons to be</p> <p>8 a polymer, albeit a very low molecular weight</p> <p>9 polymer. Most commercial polymers are hundreds</p> <p>10 of thousands to millions.</p> <p>11 Q. Of what significance to molecular</p> <p>12 weight is a breakdown of the polypropylene</p> <p>13 polymer, a change in the polypropylene polymer,</p> <p>14 will it change the molecular weight?</p> <p>15 MR. ANDERSON: Objection to form.</p> <p>16 Go ahead.</p> <p>17 A. I'm sorry, can I rehear it again?</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. The polypropylene polymer is broken,</p> <p>20 the chain is broken.</p> <p>21 A. Okay.</p> <p>22 Q. Will that change the molecular weight?</p> <p>23 A. It will lower it.</p> <p>24 Q. Page 80. After doing your analysis,</p> <p>25 you conclude in your scientific opinion that</p>
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<p>1 coating the particle, the bulk of which was</p> <p>2 polypropylene. And then I would have seen only</p> <p>3 polypropylene, what's left.</p> <p>4 This figure that's shown here</p> <p>5 represents -- keep in mind the carbonyl bands</p> <p>6 are much stronger than alkyl bands. So the fact</p> <p>7 that they're roughly the same size suggests to</p> <p>8 me that this material, as I'm looking at it</p> <p>9 here, is about 75 percent polypropylene and</p> <p>10 25 percent protein, thereabouts, plus or minus a</p> <p>11 little. And it's oxidized, because I have the</p> <p>12 1740 and the 1757. And there may be a 1730 and</p> <p>13 a 1715 that I can't see because it's buried</p> <p>14 under the 1656 band, which I could see if in the</p> <p>15 future we choose to do any more -- like sodium</p> <p>16 hypochlorite.</p> <p>17 Q. Page 72. "Molecular weight is often a</p> <p>18 crucial factor in determining material</p> <p>19 properties."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes, you do.</p> <p>22 Q. What is molecular weight?</p> <p>23 A. It's really a measure of the number of</p> <p>24 repeat units in a given polymer molecule.</p> <p>25 Monomer is the starting material, usually a</p>	<p>1 "The control and explant samples do not show a</p> <p>2 significant difference in molecular weight."</p> <p>3 Correct?</p> <p>4 A. That's correct.</p> <p>5 Q. Doesn't that mean that there's no</p> <p>6 evidence in your molecular weight analysis that</p> <p>7 polypropylene is degrading?</p> <p>8 A. It might seem so at first</p> <p>9 consideration. But remember, the only part of</p> <p>10 the polymer that seems to be degrading based on</p> <p>11 the SEM photos is the surface.</p> <p>12 So GPC is a bulk technique, I had to</p> <p>13 dissolve the inside undamaged region as well as</p> <p>14 the broken pieces, but I get one sample. The</p> <p>15 total mixture dissolved.</p> <p>16 So number one, the effect of the</p> <p>17 damaged surface -- my point here is I think if</p> <p>18 we could measure the surface we would see a loss</p> <p>19 in molecular weight, but I had no way to get</p> <p>20 enough pieces to measure the molecular weight of</p> <p>21 only the surface pieces like I did for the</p> <p>22 infrared spectra.</p> <p>23 Q. Aren't you speculating what you find?</p> <p>24 A. I am.</p> <p>25 Q. Until you have the opportunity to test</p>

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<p>1 as you've described, the fact that your</p> <p>2 molecular weight testing does not show a</p> <p>3 significant difference in molecular weight</p> <p>4 suggests that there's no degradation of the</p> <p>5 polypropylene. That's the best scientific</p> <p>6 conclusion you can reach in this data, isn't</p> <p>7 that true?</p> <p>8 A. It's one of the conclusions, yes.</p> <p>9 Q. It's --</p> <p>10 A. It's not the only one.</p> <p>11 Q. It's fair to say -- okay.</p> <p>12 Now, has Jordi Labs analyzed</p> <p>13 polypropylene mesh for other manufacturers?</p> <p>14 A. I don't run the day-to-day operations</p> <p>15 anymore, so I would have no way to answer that</p> <p>16 question. I don't know what has come in.</p> <p>17 Q. Do you know?</p> <p>18 A. I do not know.</p> <p>19 Q. Do you know whether Jordi Labs</p> <p>20 analyzed Bard mesh that was at issue in the West</p> <p>21 Virginia litigation?</p> <p>22 A. I don't know.</p> <p>23 Q. Do you know whether Bard mesh has</p> <p>24 antioxidants in it?</p> <p>25 A. I haven't been requested to analyze,</p>	<p>1 he knows it is an inappropriate form of a</p> <p>2 question.</p> <p>3 MR. THOMAS: Okay.</p> <p>4 MR. ANDERSON: If you think somebody</p> <p>5 from Jordi Labs testified there, then I think</p> <p>6 that would differ from reality.</p> <p>7 MR. THOMAS: I wasn't talking about</p> <p>8 Jordi Labs testifying.</p> <p>9 MR. ANDERSON: That's what it says.</p> <p>10 MR. THOMAS: Got you.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Dr. Jordi, are you aware that Jordi</p> <p>13 Labs conducted analysis on Bard mesh for use by</p> <p>14 the Plaintiffs in the Bard mesh litigation?</p> <p>15 MR. ANDERSON: Objection. Asked and</p> <p>16 answered.</p> <p>17 A. I am not.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. If Jordi Labs had analyzed</p> <p>20 polypropylene mesh used for pelvic floor</p> <p>21 implants and found a loss of molecular weight in</p> <p>22 that mesh, would that be relevant to your</p> <p>23 opinions in this case?</p> <p>24 MR. ANDERSON: Objection.</p> <p>25 Go ahead.</p>
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<p>1 so I don't know.</p> <p>2 Q. Do you know whether Bard mesh loses</p> <p>3 its molecular weight upon testing?</p> <p>4 A. I haven't seen the Bard mesh, so no.</p> <p>5 Q. You've not seen the work that Jordi</p> <p>6 Labs did for Plaintiffs in the Bard litigation</p> <p>7 where they -- where Jordi Labs, your company,</p> <p>8 testified the Bard mesh without antioxidants had</p> <p>9 showed a loss in molecular weight, is that true?</p> <p>10 MR. ANDERSON: Objection to form.</p> <p>11 Assumes facts not in evidence.</p> <p>12 A. Say again?</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. You've not seen the work that Jordi</p> <p>15 Labs did for Plaintiffs in the Bard litigation</p> <p>16 where they, where Jordi Labs, your company,</p> <p>17 testified the Bard mesh without antioxidants</p> <p>18 showed a loss in molecular weight?</p> <p>19 MR. ANDERSON: Same objections.</p> <p>20 A. I'm unaware. I don't know.</p> <p>21 MR. THOMAS: Are you saying it didn't</p> <p>22 happen?</p> <p>23 MR. ANDERSON: I'm saying the way you</p> <p>24 asked this question, the way you posited it as</p> <p>25 something that's true rather than asking him if</p>	<p>1 A. I don't have enough information from</p> <p>2 just that question to answer it. I'd have to</p> <p>3 know what the antioxidants were, what the levels</p> <p>4 were, and so on.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Okay. Are you suggesting by your</p> <p>7 testimony in this case that the polypropylene in</p> <p>8 the Ethicon mesh depolymerizes?</p> <p>9 A. In the Ethicon mesh?</p> <p>10 Q. Yes.</p> <p>11 A. It obviously hasn't depolymerized if</p> <p>12 the molecular weight is the same.</p> <p>13 Q. So you're not testifying that it's</p> <p>14 depolymerized?</p> <p>15 MR. ANDERSON: Objection.</p> <p>16 A. No. What I think is going on is two</p> <p>17 effects. I think we have an oxidative</p> <p>18 phenomenon, which I can show you in my report --</p> <p>19 I have the report in here somewhere. I can find</p> <p>20 it quick.</p> <p>21 (Witness reviewing document.)</p> <p>22 A. Page 6, it's possible to have -- R</p> <p>23 prime is the radical form of polypropylene. So</p> <p>24 if you get two radical polypropylene molecules</p> <p>25 that physically couple, that will double the</p>

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<p>1 molecular weight initially. It's degradation, 2 but it's actually going to increase the 3 molecular weight. At the same time we've got 4 beta scission going on, which is decreasing 5 molecular weight. And initially the two effects 6 can more or less cancel out, and you don't see a 7 net change. 8 Eventually yes, it will depolymerize, 9 but apparently this material hasn't gone that 10 far. 11 BY MR. THOMAS: 12 Q. It's the same across every sample that 13 you tested? 14 A. Yes, in this case, in this particular 15 set of samples it was. 16 Q. And it's the same with the Burkley 17 seven year dog study? 18 A. Yes. That's what Dan Burkley said, 19 yes. 20 Q. Every time you've tested the molecular 21 weight of Ethicon's mesh or gone back and 22 retested the molecular weight of Ethicon's mesh, 23 the molecular weight hasn't changed in a 24 significant manner? 25 A. No, we don't see it -- it's true, we</p>	<p>1 7846, amount of \$5,000. 2 Invoice number 7881 on September 11, 3 2013, in the amount of \$100,418.74. 4 Invoice number 7882 dated 5 September 11, 2013, in the amount of \$13,980.42. 6 Invoice 7883, dated September 11, 7 2013, in the amount of \$203,470. 8 Invoice number 7918 dated 9 September 23rd, 2013, in the amount of \$45,375. 10 Invoice number 7882 dated 11 September 11, 2013, in the amount of \$13,980.42. 12 Invoice number 7884 dated 13 September 11, 2013, in the amount of \$6,122.94. 14 Invoice number 7984 dated October 15 the 10th, 2013, in the amount of \$28,130. 16 And invoice number 8035 dated 17 October 28, 2013, in the amount of \$28,876.05. 18 To the best of your knowledge, is that 19 the total of the billing that you've made in 20 connection with your work in this case? 21 A. To this point, yes. There's no other 22 bills. I'm sure there will be another one 23 coming. 24 Q. Obviously in your work in this case 25 you've analyzed a number of different explant</p>
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<p>1 do not see a -- 2 Q. As a matter of fact, there's never 3 been a time where you've analyzed Ethicon mesh 4 used in these TVT products that shows a change 5 in molecular weight? 6 MR. ANDERSON: Objection. Asked and 7 answered. 8 But answer it again. 9 A. That's true. That's correct. 10 BY MR. THOMAS: 11 Q. Dr. Jordi, during lunch I was provided 12 with invoices from your office to Mr. Anderson. 13 I'll read these into the record, if you don't 14 mind. 15 A. That's fine. 16 Q. Do you want me to do it so you can see 17 so I do it right? 18 MR. ANDERSON: What are you trying to 19 point out, just amounts? 20 MR. THOMAS: Just the dates and 21 amounts. 22 BY MR. THOMAS: 23 Q. On August the 12th, 2013, invoice 24 7783, for \$11,250. 25 August the 28th, 2013, invoice number</p>	<p>1 samples? 2 A. Correct. 23; 24 with Batiste. 3 Q. Are you able to tell from these 4 invoices the extent to which your work has 5 focused on the Carolyn Lewis case, or is all of 6 this for the Carolyn Lewis case? 7 MR. ANDERSON: I'm not sure I 8 understand the question. It could be more legal 9 in nature, so due to that I will object. 10 BY MR. THOMAS: 11 Q. Are you able to look at these bills 12 and tell me the extent to which you worked on 13 the Lewis specific matter, for example, perhaps 14 the time when you received the Lewis explant 15 separate and apart from the others that you 16 analyzed, and determine the cost that you 17 incurred in analyzing the Lewis explant? I 18 don't know if you can or not. 19 MR. ANDERSON: I'm just going to 20 object to the form, because I think you've mixed 21 two different things. One is you're asking how 22 much of the work was case specific, and he's a 23 general expert as well as looking at the 24 specific explant of Ms. Lewis. 25 So if you want us to look at the bill</p>

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<p>1 and see just how much the cost was of the</p> <p>2 testing and the analysis for just Lewis, we will</p> <p>3 try to do that. But to mix that up and to say</p> <p>4 how much of the cost related to just Ms. Lewis,</p> <p>5 as you know at the trial he's going to be</p> <p>6 talking about all of these things.</p> <p>7 So I just want to make sure we're on</p> <p>8 the same page and that's clear, because your</p> <p>9 question was not.</p> <p>10 MR. THOMAS: Thank you. I thought my</p> <p>11 question was clear, but that's good.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Can you tell me the extent to which --</p> <p>14 MR. ANDERSON: We agree to disagree.</p> <p>15 MR. THOMAS: I understand. I'm going</p> <p>16 to try to ask the question better now.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Can you look at these invoices,</p> <p>19 Dr. Jordi, and tell me about the Lewis specific</p> <p>20 analysis that you did, and the cost of that?</p> <p>21 MR. ANDERSON: We'd have to get more</p> <p>22 material to be able to do that. We tried to</p> <p>23 bring everything in here to be able to do that,</p> <p>24 we've got lab notebooks to when those days would</p> <p>25 be as opposed to the billing. The problem is</p>	<p>1 there next to it. That would be the 1740.</p> <p>2 Q. Let's go one at a time.</p> <p>3 The first one you said a minute ago,</p> <p>4 the carbonyl band where?</p> <p>5 A. Around 1759. Some of these, there's</p> <p>6 no valley there, so the machine didn't actually</p> <p>7 label it. If you go to the next page, 72, it's</p> <p>8 very similar, you'll see there it does have a</p> <p>9 slight valley, so the machine calls it 1761. I</p> <p>10 think we showed another one that was 1757. It's</p> <p>11 in that region, all of them.</p> <p>12 Q. Is there any discussion in your report</p> <p>13 anywhere, specifically text, about your findings</p> <p>14 with respect to Carolyn Lewis?</p> <p>15 MR. ANDERSON: You mean in one place?</p> <p>16 MR. THOMAS: Anywhere.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. About "this is what I find wrong with</p> <p>19 Carolyn Lewis based on this analysis."</p> <p>20 MR. ANDERSON: He's pointing to one</p> <p>21 right now. I don't understand.</p> <p>22 MR. THOMAS: I understand that, Ben.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Do you explain anywhere --</p> <p>25 A. I explain the principles in the</p>
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<p>1 the billing is through a time period, so we'd</p> <p>2 have to try to look and match up the time period</p> <p>3 in the lab notebook to when it was received with</p> <p>4 the time period on the invoice. We're happy to</p> <p>5 take the time to try to do that.</p> <p>6 MR. THOMAS: I'd like to use my time</p> <p>7 better than that.</p> <p>8 I'm going to mark these invoices</p> <p>9 collectively as Exhibit Number 5.</p> <p>10 MR. ANDERSON: Sure.</p> <p>11 (Whereupon, Jordi Exhibit Number 5,</p> <p>12 Group of invoices from Jordi Labs, was</p> <p>13 marked for identification.)</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Dr. Jordi, what are your opinions with</p> <p>16 respect to the mesh explant of Carolyn Lewis?</p> <p>17 If you're going to your report, tell me where</p> <p>18 you're going, please.</p> <p>19 A. As soon as I get there and find</p> <p>20 something, I will.</p> <p>21 Page 71. So that's the infrared, one</p> <p>22 of the shards from Carolyn Lewis. Sample 13674</p> <p>23 showing carbonyl band highlighted there in</p> <p>24 yellow.</p> <p>25 There's a second shoulder you can see</p>	<p>1 conclusions. It applies to all the explanted</p> <p>2 samples, including Carolyn Lewis, but not</p> <p>3 specifically Carolyn Lewis.</p> <p>4 Q. Okay. So there are no specific</p> <p>5 opinions in your report that relate to Carolyn</p> <p>6 Lewis, is that fair?</p> <p>7 MR. ANDERSON: Objection to form.</p> <p>8 THE WITNESS: Answer?</p> <p>9 MR. ANDERSON: You can answer.</p> <p>10 A. Not that I -- no.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Okay. So it's correct that there are</p> <p>13 no specific opinions to Carolyn Lewis in your</p> <p>14 report, correct?</p> <p>15 MR. ANDERSON: Objection.</p> <p>16 A. Well, there are.</p> <p>17 MR. ANDERSON: That's unfair.</p> <p>18 Go ahead.</p> <p>19 A. There are, because it's the photos.</p> <p>20 You want it text, but it's in the presence of</p> <p>21 the printed results.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Okay. But you don't describe anywhere</p> <p>24 in your report what, for example, Figure 81</p> <p>25 means to you in your interpretation, correct?</p>

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<p>1 A. I describe in general what all these 2 figures like this mean. So if it's a carbonyl 3 for Carolyn Lewis, or it's a carbonyl for any of 4 the other explants, it's the same meaning. 5 Q. I see. 6 So when you point out this shoulder on 7 Page 71 in Figure 81 that's not marked in any 8 way, that's something that you see on the 9 drawing, that you're the one who identifies that 10 and can only testify to that because you can see 11 it; fair? 12 MR. ANDERSON: Objection to the form 13 of the question. 14 Go ahead. 15 A. Well, due to my experience reading 16 FTIRs, yes, I can see it. Anyone else with 17 equivalent experience would see it, too. 18 BY MR. THOMAS: 19 Q. Well, I'm lawyer and a history major, 20 would you expect me to be able to figure that 21 out? 22 MR. ANDERSON: No comment. 23 A. No comment. 24 BY MR. THOMAS: 25 Q. Okay. Certainly not apparent to</p>	<p>1 Carolyn Lewis mesh? 2 A. The cracking. 3 Q. That's the perpendicular cracking? 4 A. The perpendicular cracking. And then 5 we also have a parallel flaking which you can 6 see at the top, at the bend where it goes -- 7 particles getting ready to come off. And 8 there's also tissue on top of that. 9 Q. Now, is this the portion of the mesh 10 that you tested with FTIR analysis? 11 A. It is not. 12 Q. Okay. 13 A. Remember, we didn't want to cause any 14 stress or strain on these meshes, so we simply 15 sent it imbedded in tissue. For the IR you must 16 remove the tissue in order to get the spectrum. 17 Q. Okay. What else do you have for 18 Carolyn Lewis? 19 A. Okay. SEM-EDX, let's find that chart. 20 58, Page 58. 21 Q. On Figure 71, you have -- is that a 22 different image still than the one that was on 23 48? 24 A. Yeah. It is, yes. 25 Q. All right. And the J8041 means what?</p>
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<p>1 somebody without your training as to what is 2 shown in Figure 81. Would you agree with that? 3 A. Without training, none of us could 4 read an infrared. We all have to learn it. 5 Q. What else do you have specific in your 6 report to Carolyn Lewis? 7 A. Well, see if I can find the SEM and 8 the SEM-EDX. See if we can find the SEM. We 9 can just work our way through. 10 Page 48 is the SEM. 11 Q. Okay. Let's stop there. 12 On Page 48 you have Figure 59, and 13 that's -- what does that represent? 14 A. That's the tissue with the mesh 15 imbedded in the tissue. 16 Q. Okay. 17 A. And then the picture 60 is of the 18 actual region that they were -- we were able to 19 get -- I was able to get a photo micrograph of 20 the fiber. 21 Q. Do you know which part of Figure 59 is 22 depicted in Figure 60? 23 A. No, not specifically. 24 Q. What is it about Figure 60 that 25 suggests to you that there's degradation in the</p>	<p>1 A. That's the job number. 2 Q. Okay. 3 A. 13674 is sample number. 4 Q. And what does this show you? 5 A. The boxes are the regions that were 6 tested. So like Spectrum 3, if you go down to 7 the -- you can see the pink box at the top for 8 Spectrum 3, right? Now, if you go down below 9 you'll see in yellow Spectrum 3, upper right 10 corner of the bottom box. 11 Do you see that? 12 Q. Yes. 13 A. That's just telling you that the 14 yellow spectrum is this region of the specimen, 15 region 3. And so you'll see you have a peak, a 16 fairly large peak for oxygen, a huge peak for 17 carbon, sodium, aluminum which is just a sample 18 pan that doesn't mean anything, phosphorus and 19 sulfur are at fairly large peaks on this region 20 of the spectrum. 21 Now, that's the cracked region, and 22 has a large amount of oxygen. But we also 23 thought that the cracked region also, well, 24 uniformly showed higher oxygen levels, but it 25 also showed higher, many times, phosphorus and</p>

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<p>1 sulfur levels. So that could mean phosphate and</p> <p>2 sulfate which also contain oxygen, so the</p> <p>3 increased oxygen in that region could have been</p> <p>4 from buffers as well as just literally the</p> <p>5 oxidation type oxygen.</p> <p>6 So you want to go to region of the</p> <p>7 polymer that wasn't cracked, there's Spectrum 4.</p> <p>8 And that is the red one. It's hard to read in</p> <p>9 the picture but it's -- the red is Spectrum 4.</p> <p>10 Now you see -- you still see an oxygen peak,</p> <p>11 although it's lower in the Spectrum 3, but now</p> <p>12 the sodium is almost totally gone, and the</p> <p>13 phosphorus and sulfur are basically gone</p> <p>14 completely.</p> <p>15 So what this is telling me is even in</p> <p>16 the non-cracked region, I have a higher than</p> <p>17 baseline level of oxygen. If you want to see</p> <p>18 that in another --</p> <p>19 Q. Before you do that, may I ask you</p> <p>20 another question?</p> <p>21 A. Sure.</p> <p>22 Q. I don't want to interrupt you.</p> <p>23 A. Go ahead.</p> <p>24 Q. Spectrum 4 shown in red, are you</p> <p>25 suggesting that what you're testing in Spectrum</p>	<p>1 or sulphur. That is the increased oxygen that I</p> <p>2 call oxidation.</p> <p>3 Q. Okay. Again, so Spectrum 3 is meant</p> <p>4 to be testing the oxidized polypropylene,</p> <p>5 correct?</p> <p>6 A. Right. That's why we ran it there</p> <p>7 first.</p> <p>8 Q. Spectrum 4 is designed to testify --</p> <p>9 excuse me.</p> <p>10 Spectrum 4 is designed to test what</p> <p>11 you believe to be clean polypropylene?</p> <p>12 A. Let's phrase it this way.</p> <p>13 Not yet degraded. Not yet cracked.</p> <p>14 But I didn't know whether -- if it has increased</p> <p>15 oxygen in it, that means it's on its way to</p> <p>16 cracking.</p> <p>17 What I believe is happening is layer</p> <p>18 after layer after layer of this stuff is going</p> <p>19 to crack depending on the implantation time.</p> <p>20 The first layer is going to go quickest because</p> <p>21 it's -- remember the outer layer is less</p> <p>22 crystalline, remember the paper I showed you</p> <p>23 earlier, and so it's going to go first. And</p> <p>24 when it peels off, as some of it's flaked off</p> <p>25 here, then we expose more underlying fresh</p>
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<p>1 4 is pure polypropylene?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Without any kind of</p> <p>4 contamination at all?</p> <p>5 A. We got away from the -- you can see</p> <p>6 this white material here, which would be the</p> <p>7 polypropylene -- which would be tissue.</p> <p>8 Q. Okay.</p> <p>9 A. Which you might call biofilm. We'll</p> <p>10 have to agree to disagree or agree to agree and</p> <p>11 use both terms interchangeably. So I wanted to</p> <p>12 get away from that as much as possible, so we</p> <p>13 ran a cleaner spectra -- cleaner region that</p> <p>14 didn't have cracks in it.</p> <p>15 Now, when I look at this, I see this</p> <p>16 cracked material in many places is flaked off.</p> <p>17 You can see the edge over here on the right</p> <p>18 where the piece has actually come off and it's</p> <p>19 gone. You can see the edge where it was. And</p> <p>20 the same is true on the other side. But on this</p> <p>21 left side of it, it's clean. And then left of</p> <p>22 it up there's really nothing but straight --</p> <p>23 pretty much straight clean-ish polypropylene.</p> <p>24 So we ran a spectrum of that, and we still saw</p> <p>25 increased oxygen. But no increased phosphorus</p>	<p>1 surface, which then begins to itself oxidize as</p> <p>2 reflected in the increased oxygen even in that</p> <p>3 region, which is the red peak for oxygen.</p> <p>4 Q. What is Spectrum 2?</p> <p>5 A. We just didn't show it.</p> <p>6 Q. Did you run the data?</p> <p>7 A. Yeah, I could show it. I could get</p> <p>8 it. I don't have it with me.</p> <p>9 Q. It's not in your report?</p> <p>10 A. It might be. Do you want to see if I</p> <p>11 can find it?</p> <p>12 Q. Just curious, yes.</p> <p>13 A. Glad to try. If we don't have it, we</p> <p>14 certainly can get it.</p> <p>15 Q. It won't be in the controls, will it?</p> <p>16 A. That doesn't mean anything, because</p> <p>17 I've got -- this is LCMS. It's not in exact.</p> <p>18 Here we go. Now I've got --</p> <p>19 (Witness reviewing document.)</p> <p>20 MR. ANDERSON: We'll go off the record</p> <p>21 while we're looking. Is that okay with you,</p> <p>22 Dave?</p> <p>23 MR. THOMAS: Yes.</p> <p>24 (Off the record discussion.)</p> <p>25 (Whereupon, a recess was taken from</p>

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<p>1 2:47 p.m. to 2:53 p.m.)</p> <p>2 A. He's got a box on the Spectrum 2 so</p> <p>3 I'm almost sure it's run, so we'll just have --</p> <p>4 if you want that spectrum, I don't see it in</p> <p>5 the -- number one, the reason it's not there is</p> <p>6 because it's also on a cracked region just like</p> <p>7 Spectrum 3 is, so what it's going to look like</p> <p>8 is the higher -- the one in yellow, it's just a</p> <p>9 duplicate of the one in yellow.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. I understand, Doctor. So for reasons</p> <p>12 I'm sure you understand, I'd like to have a copy</p> <p>13 of it.</p> <p>14 MR. ANDERSON: Yes.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Just so the record is clear, you've</p> <p>17 searched your files that you brought with you --</p> <p>18 A. I can't find it.</p> <p>19 Q. -- and you're unable to find the</p> <p>20 Spectrum 2 data that appears on Page 58 of</p> <p>21 Exhibit 1?</p> <p>22 MR. ANDERSON: Is that correct?</p> <p>23 A. That's correct.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. Thank you.</p>	<p>1 bottom of Table 5 for sample ID number 13674.</p> <p>2 A. Correct. So -- and now we compare</p> <p>3 that with the first heat effusion for the</p> <p>4 control samples, you can see that they range</p> <p>5 from 93, 79, 82, 86. Table 7 probably says it</p> <p>6 best. We do -- for the samples, we had a couple</p> <p>7 samples that didn't show any cracking on the</p> <p>8 average of -- FLP for those samples was 86.6</p> <p>9 kilograms per gram -- or joules per gram, sorry.</p> <p>10 And moderate cracking at 81.2, and highly</p> <p>11 cracked at 75.1. And here we're at 69.77, so</p> <p>12 we're in that highly cracked region in terms of</p> <p>13 this measurement.</p> <p>14 Q. Does this DSC testing that you did,</p> <p>15 which you used to suggest that this is evidence</p> <p>16 of oxidation, does this also capture the extent</p> <p>17 to which there are any impurities in the sample?</p> <p>18 A. I would say, number one, it doesn't</p> <p>19 necessarily correlate with oxidation, although</p> <p>20 it could. But it also correlates with possible</p> <p>21 stress cracking.</p> <p>22 Q. Okay.</p> <p>23 A. Because there's less crystallinity.</p> <p>24 Q. Let me ask this question again.</p> <p>25 You are using this DSC data to suggest</p>
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<p>1 Okay. We were talking about evidence</p> <p>2 that you had specific to Carolyn Lewis.</p> <p>3 A. So the net result here is that we have</p> <p>4 oxygen in the clean looking, undegraded looking</p> <p>5 region of the fiber that's under the cracked</p> <p>6 region suggesting that it's beginning to oxidize</p> <p>7 as well, but it's not enough yet that it's</p> <p>8 actually cracked.</p> <p>9 Q. Okay.</p> <p>10 A. So we'll go to DSC.</p> <p>11 Okay. So the first thing you do is</p> <p>12 look at Table 5, then look at the heat effusion.</p> <p>13 First heat is 69.77 joules per gram.</p> <p>14 Do you see that?</p> <p>15 Q. No.</p> <p>16 A. Table 5, last entry in the table,</p> <p>17 under heat effusion for TM.</p> <p>18 Q. What page are you on?</p> <p>19 A. Page 63.</p> <p>20 Q. I'm sorry, I was on 62.</p> <p>21 A. Go up. First table, Table 5.</p> <p>22 Q. Okay.</p> <p>23 A. Last line of that table, and then the</p> <p>24 middle entry is 69.77.</p> <p>25 Q. I have that. That's on Page 63 at the</p>	<p>1 that the lower melting point reflects either</p> <p>2 oxidation or stress -- environmental stress</p> <p>3 cracking. Does it also capture any impurities</p> <p>4 that may have been in the sample?</p> <p>5 A. If there were impurities in the</p> <p>6 sample, they would also tend to lower the melt</p> <p>7 point.</p> <p>8 Q. Okay. Are you able to tell from this</p> <p>9 DSC testing the extent to which the values</p> <p>10 reflect oxidation, environmental stress</p> <p>11 cracking, as opposed to impurities?</p> <p>12 A. No.</p> <p>13 Q. All right. Now, what is it about</p> <p>14 Ms. Lewis's values that suggest to you that</p> <p>15 there's oxidation or environmental stress</p> <p>16 cracking going on?</p> <p>17 A. The value of her heat effusion is very</p> <p>18 low, 69.77.</p> <p>19 Q. And you're unable to tell me the</p> <p>20 extent to which that is oxidation and</p> <p>21 environmental stress cracking as opposed to</p> <p>22 impurities?</p> <p>23 A. Well, I don't think -- we're not</p> <p>24 talking about oxidation, we're talking about</p> <p>25 environmental stress cracking. They're two</p>

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<p>1 different, totally different mechanisms for</p> <p>2 degradation of the polymer. Both are</p> <p>3 degradation, but one is physical mechanical</p> <p>4 degradation where the chains are forced to part</p> <p>5 and they crack, and the other is actual literal</p> <p>6 oxidation. They're different.</p> <p>7 Q. Let me ask the question different,</p> <p>8 because that wasn't what I was trying to get at.</p> <p>9 It's fair to say you don't know the</p> <p>10 extent to which impurities in the test sample</p> <p>11 may have contributed to the low heat effusion</p> <p>12 values for Carolyn Lewis as reflected on Table 5</p> <p>13 on Page 63, correct?</p> <p>14 A. Correct.</p> <p>15 Q. Thank you.</p> <p>16 What else do you have for Ms. Lewis?</p> <p>17 A. FTIR. Page 71, Figure 81, Figure 82.</p> <p>18 We have, again, the carbonyl that are on 1760</p> <p>19 and another one around -- the shoulder is about</p> <p>20 1740, that's under that large 1653 amide 1 band.</p> <p>21 Q. Okay. Let me stop you here for a</p> <p>22 second.</p> <p>23 Figure 81 says "Microscopy images</p> <p>24 showing particles recovered from explant sample</p> <p>25 13674 (particle 1)."</p>	<p>1 Table 18, Page 92. The control samples showed</p> <p>2 anywhere from 71 million counts to 92 million</p> <p>3 counts. In this case, we also ran formalin</p> <p>4 treated control samples which showed levels that</p> <p>5 were right in the middle of the controls, some</p> <p>6 were higher, some were lower, fit the normal</p> <p>7 range for controls, indicating formalin didn't</p> <p>8 extract the lauryl thiodipropionate.</p> <p>9 So the level for Ms. Lewis was 611,000</p> <p>10 compared to 80 million, so it's about in the 2</p> <p>11 percent range left for the lauryl</p> <p>12 thiodipropionate antioxidant compared to the</p> <p>13 controls, and the formalin controls.</p> <p>14 Q. Okay. Let's talk about Page 92 for a</p> <p>15 minute.</p> <p>16 Here you have control samples again?</p> <p>17 A. Right.</p> <p>18 Q. Why do you do a duplicate control like</p> <p>19 you do on 3422128? Do you have do that as a</p> <p>20 test?</p> <p>21 A. Yes. A test to see how reproducible</p> <p>22 the material itself might be.</p> <p>23 Q. Okay. Or how reliable your test might</p> <p>24 be?</p> <p>25 A. Well, I suppose that's another way to</p>
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<p>1 How many particles did you remove from</p> <p>2 Ms. Lewis's explant?</p> <p>3 A. Didn't count them. Lots. The surface</p> <p>4 sluffs off.</p> <p>5 Q. Did you analyze any others? This is</p> <p>6 noted as particle 1. That suggests to me that</p> <p>7 there are others that are identified?</p> <p>8 A. Right.</p> <p>9 No.</p> <p>10 Q. No what? No, you don't know, or no --</p> <p>11 A. No, it wasn't the only one analyzed.</p> <p>12 Q. Do you still have the others?</p> <p>13 A. I don't know. I have to check.</p> <p>14 Q. Was it your practice to keep those</p> <p>15 things following an experiment like this?</p> <p>16 A. If there was anything to keep, yes.</p> <p>17 It was very, very minimal samples here.</p> <p>18 Q. Are you able to tell me how many</p> <p>19 particles there are --</p> <p>20 A. No.</p> <p>21 Q. -- from Ms. Lewis's sample?</p> <p>22 A. I'm not.</p> <p>23 Q. Anything else from Ms. Lewis?</p> <p>24 (Witness reviewing document.)</p> <p>25 A. The amount of lauryl thiodipropionate,</p>	<p>1 look at it.</p> <p>2 Q. And --</p> <p>3 A. But we ran standards, and we get the</p> <p>4 same -- we make the injection standards twice,</p> <p>5 we get the same area, so that's not --</p> <p>6 Q. My point being is that for control</p> <p>7 sample 3422128, you've got 71,633,460, and then</p> <p>8 you test exactly the same mesh in a different</p> <p>9 place in the mesh in the duplicate control and</p> <p>10 you get 96 thousand 522 --</p> <p>11 A. 96 million, yes.</p> <p>12 Q. Thank you.</p> <p>13 -- 96,522,909, which is about</p> <p>14 40 percent more than your other control.</p> <p>15 A. We could be extracting regions of the</p> <p>16 mesh that have flaked off the polypropylene that</p> <p>17 we see flaked off in the IR, and what we're</p> <p>18 extracting here is a residual, call it clean</p> <p>19 mesh.</p> <p>20 Q. You don't know why there's a</p> <p>21 40 percent difference in the test of the same</p> <p>22 mesh?</p> <p>23 A. No. But I would suspect there's a</p> <p>24 change in the mesh, either because the mesh</p> <p>25 itself isn't uniform, or because maybe it's</p>

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<p>1 because the polypropylene, the cracked</p> <p>2 polypropylene is gone in that region at that</p> <p>3 point, and we are just extracting the enriched</p> <p>4 area only.</p> <p>5 Q. Okay.</p> <p>6 A. I think that would easily account for</p> <p>7 that difference.</p> <p>8 Q. But do you have a scientific</p> <p>9 explanation for the reasons why the same piece</p> <p>10 of mesh tests differently by some 28 million</p> <p>11 DAs?</p> <p>12 MR. ANDERSON: Other than what he just</p> <p>13 testified to?</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Scientific explanations or reasonable</p> <p>16 scientific certainty, do you have the answer to</p> <p>17 the question?</p> <p>18 A. I think I just gave it, my estimate of</p> <p>19 the --</p> <p>20 Q. Is that your opinion to a reasonable</p> <p>21 degree of scientific certainty what happened, or</p> <p>22 are you just positing it as something you need</p> <p>23 to test?</p> <p>24 A. I think it's reasonable, yes.</p> <p>25 Q. Reasonable degree of scientific</p>	<p>1 A. True.</p> <p>2 Q. Okay. Anything else on Carolyn Lewis?</p> <p>3 A. I think we've pretty well covered it.</p> <p>4 I think I can show you -- well, one</p> <p>5 other thing that might be of interest if we look</p> <p>6 at Table -- go back and look at that table for a</p> <p>7 minute longer, and just pick arbitrarily 13411,</p> <p>8 it has 12 million area counts for --</p> <p>9 Q. What page are you on, please?</p> <p>10 A. Same page, 92.</p> <p>11 Q. I put mine away. I have to figure out</p> <p>12 the pages.</p> <p>13 A. Okay.</p> <p>14 Q. Okay.</p> <p>15 A. So now that's a relatively higher</p> <p>16 level than any of the others, isn't it, for the</p> <p>17 antioxidants, so what would I expect to see? I</p> <p>18 would expect to see less cracking in that sample</p> <p>19 if I went back and my theory is right, my</p> <p>20 scientific opinion is right. So let's go look</p> <p>21 at the SEM photograph for 13411, which will be</p> <p>22 the actual degree of cracking, and just see if</p> <p>23 it correlates or not.</p> <p>24 Q. What page is it?</p> <p>25 A. I'm looking. I'm getting close. It's</p>
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<p>1 certainty, is that the answer to the problem?</p> <p>2 A. Yes. I think it's reasonable degree</p> <p>3 of scientific certainty with this one. Because</p> <p>4 we didn't extract -- the formalin didn't do</p> <p>5 anything to the polymer in this case, showing me</p> <p>6 it's not coming out of the polymer -- at least</p> <p>7 the formalin isn't able to extract it out of the</p> <p>8 polymer because you're right in the heart of the</p> <p>9 average.</p> <p>10 Q. Well, if you look at 3405405, the</p> <p>11 control is 79, and the formalin control is 10</p> <p>12 million less, isn't it? And the same with</p> <p>13 3422128, you've got 96,522,000, and the control</p> <p>14 was 17 million less, isn't it?</p> <p>15 A. Do you have any idea, though, what --</p> <p>16 how the ratios are working out here? You're</p> <p>17 talking about a 20 percent change down here, and</p> <p>18 I'm talking about a 100-fold change up above.</p> <p>19 Q. I know that.</p> <p>20 A. It's irrelevant.</p> <p>21 Q. Except we don't know how long these</p> <p>22 mesh explants were in formalin, do we?</p> <p>23 A. We put these other ones in formalin</p> <p>24 and nothing happened.</p> <p>25 Q. For two days, right?</p>	<p>1 37.</p> <p>2 Q. Page 37?</p> <p>3 A. Right. I would expect to see a low</p> <p>4 degree of cracking due to the high level of</p> <p>5 antioxidant still there, and there it is. It's</p> <p>6 minimally cracked.</p> <p>7 Q. That's the one photo you have of all</p> <p>8 this mesh?</p> <p>9 MR. ANDERSON: What?</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Strike that, I'm sorry.</p> <p>12 So you point to Figure 38 on Page 37</p> <p>13 as suggesting that -- suggesting what?</p> <p>14 A. Minimal, this is what we would call</p> <p>15 minimal cracking.</p> <p>16 Q. Okay.</p> <p>17 A. And it correlates with a high level of</p> <p>18 antioxidant. So it's being protected, doesn't</p> <p>19 react, doesn't crack. Or it doesn't crack as</p> <p>20 much, it obviously is still cracking some, but</p> <p>21 it's minimal.</p> <p>22 Q. Anything else for Carolyn Lewis?</p> <p>23 A. No.</p> <p>24 Q. Let's go now to the Batiste report.</p> <p>25 A. Okay.</p>

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<p>1 Q. The Batiste report has been marked as</p> <p>2 Exhibit Number 2.</p> <p>3 MR. THOMAS: Just for the record, I</p> <p>4 just got this late Monday night, and I've had a</p> <p>5 chance to go through it a little. We'll reserve</p> <p>6 on this. I know you disagree with that, but we</p> <p>7 may reserve to come back to ask more questions</p> <p>8 about this report at a later time.</p> <p>9 MR. ANDERSON: I mean I do object to</p> <p>10 it, because there was an agreement made between</p> <p>11 Christy Jones and Rich Freese, and they agreed</p> <p>12 that in the -- in order to help both sides,</p> <p>13 because everyone has a lot going on, that there</p> <p>14 was an agreement that you guys wanted to take --</p> <p>15 in fact, your attorneys from -- or the attorneys</p> <p>16 from Butler Snow -- I have to put this on the</p> <p>17 record. If you're going to say you're going to</p> <p>18 reserve the right, I'm going to object and I'm</p> <p>19 going to put the reasons on.</p> <p>20 Attorneys from Butler Snow reached out</p> <p>21 and said "any of the same experts who are going</p> <p>22 to be in both Lewis and Batiste, we'd like to</p> <p>23 try to take their depositions at the same time</p> <p>24 so we don't have to come back and everybody fly</p> <p>25 around the country and do them at different</p>	<p>1 Q. (Indicating).</p> <p>2 MR. ANDERSON: 28th.</p> <p>3 A. Should be the 28th? I guess. We were</p> <p>4 all -- this was just taken out of the patient, I</p> <p>5 believe, most recently, so we've been working on</p> <p>6 it.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Please understand I've got to mark</p> <p>9 that one, too, just in case there's something</p> <p>10 different.</p> <p>11 A. I don't think you're going to be</p> <p>12 finding any differences.</p> <p>13 Q. I'm hopeful I won't.</p> <p>14 MR. ANDERSON: Not a lot I would bet</p> <p>15 on, but that one I will bet you there's</p> <p>16 absolutely no differences in that report other</p> <p>17 than that date.</p> <p>18 MR. THOMAS: Just for the record, I'm</p> <p>19 marking as Exhibit Number 6 what Dr. Jordi had</p> <p>20 in his file as being the final report for Linda</p> <p>21 Batiste dated October 30th, 2013. The one that</p> <p>22 was produced to us that's been marked as</p> <p>23 Exhibit 2 is October 28th.</p> <p>24</p> <p>25</p>
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<p>1 times." So we agreed to try to do that.</p> <p>2 Also the agreement was that within 48</p> <p>3 hours of the depo we would get -- we said we'd</p> <p>4 try within 48 hours of the depo, which we did,</p> <p>5 to send over the Batiste results.</p> <p>6 And that was the agreement between the</p> <p>7 parties.</p> <p>8 MR. THOMAS: I understand. I just --</p> <p>9 MR. ANDERSON: So I don't see how you</p> <p>10 can then reserve your right after your side has</p> <p>11 already made an agreement, and we're doing it</p> <p>12 exactly the way your side wanted to.</p> <p>13 MR. THOMAS: I'm not sure anybody</p> <p>14 contemplated getting 278 pages, but I get it. I</p> <p>15 just need to make that statement.</p> <p>16 MR. ANDERSON: After getting a</p> <p>17 thousand on the others, I would think that would</p> <p>18 be reasonable. But go ahead with your</p> <p>19 questions.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Doctor, when did you prepare the final</p> <p>22 report of Linda Batiste? It's dated October</p> <p>23 the 28th, 2013, would that be it?</p> <p>24 A. The final date I have is October 30th,</p> <p>25 2013. It's the same. You've got --</p>	<p>1 (Whereupon, Jordi Exhibit Number 6,</p> <p>2 10/30/13 Final Report for Linda</p> <p>3 Batiste, was marked for</p> <p>4 identification.)</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Mine is two-sided, and it's twice as</p> <p>7 big as yours.</p> <p>8 A. Yes, sir. No.</p> <p>9 MR. ANDERSON: This is the rest of the</p> <p>10 data.</p> <p>11 A. This is the rest of it.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Just for the record, I didn't realize</p> <p>14 there was a second set. So we have all of it,</p> <p>15 the data makes it twice as big as mine, as it</p> <p>16 should be. Thank you.</p> <p>17 Okay. Doctor, do you intend to rely</p> <p>18 on the testing that you did in the Carolyn Lewis</p> <p>19 case in support of your opinions in the Batiste</p> <p>20 case?</p> <p>21 A. Yes. They're the same, the same</p> <p>22 analyses, yes.</p> <p>23 Q. My question is a little different.</p> <p>24 You did 22 plus, 22 or 23 --</p> <p>25 A. 23.</p>

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<p>1 Q. -- 23 explant analyses of other 2 patients -- 3 A. Yes. 4 Q. -- that are not included in your 5 analysis in the Batiste case. 6 Do you intend as a part of your 7 opinions in Batiste to rely on your work that 8 you did in Carolyn Lewis? 9 MR. ANDERSON: I can tell you as his 10 attorney that's exactly what we're going to do, 11 because there is no report requirement in Texas. 12 MR. THOMAS: Just asking. 13 MR. ANDERSON: Let me just finish, 14 because he may not understand the legal 15 ramifications and what's going on as between a 16 state court requirement and a Federal Court 17 requirement. And there is no reporting 18 requirement in Texas state court. 19 But we did agree, even though there is 20 no reporting requirement, that we would provide 21 data to make it easier for you guys to take a 22 deposition, even though we don't have to provide 23 a report. So we did that, and we gave it to you 24 48 hours before the depo, like you asked. 25 So is he going to rely on all of his</p>	<p>1 same testing for Ms. Batiste as you did for the 2 analysis in Exhibit 1? 3 A. Yes. 4 Q. Is it appropriate to use the -- strike 5 that. 6 Can we rely on your analysis in 7 Exhibit Number 1 with respect to the various 8 tests that we've talked about all day today in 9 understanding how you conducted the test for 10 Linda Batiste? 11 A. It was run the same way. 12 Q. So any discussions that we've had 13 today about your methodology, your controls, 14 your results in the Carolyn Lewis report, 15 Exhibit Number 1, would apply equally to the 16 Linda Batiste report, Exhibit 2? 17 A. Yes. 18 Q. All right. For Linda Batiste, you 19 have a series of fiber mesh control samples. 20 Are these new mesh control samples different 21 from the mesh control samples you analyzed in 22 Carolyn Lewis? 23 (Witness reviewing documents.) 24 A. They're the same. 25 BY MR. THOMAS:</p>
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<p>1 opinions in this case in Texas? You bet. 2 MR. THOMAS: Thank you. 3 BY MR. THOMAS: 4 Q. The testing that you did in the 5 Batiste case differs from the testing that you 6 did in the Carolyn Lewis case, I think. 7 A. In what way? 8 Q. I don't think you did as much. 9 A. Let me see. 10 (Witness reviewing document.) 11 BY MR. THOMAS: 12 Q. I don't think you did the PYMS in 13 Batiste. 14 A. Yeah, we did, it's right here 15 (indicating). 16 MR. ANDERSON: Page 44. 17 A. Page 44. 18 BY MR. THOMAS: 19 Q. That shows you how close we are. 20 Thank you. I apologize. 21 A. We did the GPC. 22 MR. ANDERSON: There's no question 23 pending right now. 24 BY MR. THOMAS: 25 Q. Was it your goal, Doctor, to do the</p>	<p>1 Q. Okay. And how can you tell they're 2 the same; by the test numbers? 3 A. Same numbers. Table 1 on both. 4 Q. All right. 5 A. Page 6 versus Page 13 in the 6 Exhibit 1. 7 Q. Not that this makes any difference to 8 the ultimate test, do you know whether they were 9 all TVT Classics or TVT-Os? 10 MR. THOMAS: Or do you know the answer 11 to that? 12 MR. ANDERSON: Three TVT, three TVT-O. 13 MR. THOMAS: Thank you. 14 MR. ANDERSON: That's borne out in the 15 photographs in some of the extra stuff we 16 haven't gone through, for obvious reasons. 17 MR. THOMAS: Thank you. 18 BY MR. THOMAS: 19 Q. I'm looking at the "Summary of 20 Results." 21 A. Page, please? 22 Q. Page 3. It says "A series of mesh 23 control samples and one explant sample received 24 by Jordi Labs." 25 Just for the record, we just</p>

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<p>1 established that the mesh control samples are</p> <p>2 the same control samples that you used for your</p> <p>3 comparisons with Carolyn Lewis in Exhibit 1,</p> <p>4 correct?</p> <p>5 A. Correct.</p> <p>6 Q. And the explant sample is for Linda</p> <p>7 Batiste who is the Plaintiff in the Texas</p> <p>8 action, right?</p> <p>9 A. Correct.</p> <p>10 Q. "Upon handling, it was observed that</p> <p>11 the explant sample showed some decreased</p> <p>12 elasticity as compared to the control fiber mesh</p> <p>13 samples."</p> <p>14 Again, this represents the same</p> <p>15 reporting that you made in the Carolyn Lewis</p> <p>16 case about your handling of the mesh explant as</p> <p>17 compared to the control?</p> <p>18 A. That's right.</p> <p>19 Q. And do you have any recollection in</p> <p>20 the Batiste matter for comparing the explant to</p> <p>21 the formalin control samples?</p> <p>22 A. Formalin control sample, no, I don't.</p> <p>23 I felt the explanted material was rigid, and the</p> <p>24 pristine felt very friable.</p> <p>25 Q. Okay. Next paragraph, "Cracking in</p>	<p>1 scanning calorimetry analysis showed no change</p> <p>2 in crystallinity for the cracked explant sample</p> <p>3 compared with the control samples."</p> <p>4 What does that mean?</p> <p>5 A. That means that the crystallinity</p> <p>6 didn't change, and the sample won't be more</p> <p>7 likely to be subjected to environmental stress</p> <p>8 cracking.</p> <p>9 Q. Okay.</p> <p>10 A. Any damage we see would have to be</p> <p>11 oxidative type damage.</p> <p>12 Q. So can we eliminate from the Linda</p> <p>13 Batiste analysis any environmental stress</p> <p>14 cracking?</p> <p>15 A. Yes, you can eliminate the DSC data if</p> <p>16 you want, because it's going to say there's no</p> <p>17 change.</p> <p>18 Q. Okay. So you have no molecular weight</p> <p>19 change and no DSC change?</p> <p>20 A. That's correct. In this one sample.</p> <p>21 Q. I understand.</p> <p>22 Do you know when Ms. Batiste had her</p> <p>23 surgery to remove her explant?</p> <p>24 A. I don't know the exact date, no. It</p> <p>25 was recent, within the last couple weeks,</p>
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<p>1 the explant sample was observed to propagate in</p> <p>2 a direction perpendicular to the fiber draw</p> <p>3 direction. It was noted to be primarily on the</p> <p>4 fiber surface."</p> <p>5 That's the same finding that you made</p> <p>6 for Carolyn Lewis?</p> <p>7 A. Yes, that will be reflected in the</p> <p>8 photos, SEM graphs.</p> <p>9 Q. "Analysis" -- I'm down in next</p> <p>10 paragraph now -- "analysis of the explanted</p> <p>11 fiber mesh by GPC-HT indicated that large scale</p> <p>12 molecular weight degradation had not occurred in</p> <p>13 the samples."</p> <p>14 The same finding that you had in</p> <p>15 Carolyn Lewis?</p> <p>16 A. Absolutely.</p> <p>17 Q. And when you say "large scale," the</p> <p>18 fact of the matter is you found no significant</p> <p>19 change in molecular weight; true?</p> <p>20 A. In this sample we didn't see a change</p> <p>21 in the -- oh, molecular weight you're saying?</p> <p>22 Q. Yes.</p> <p>23 A. No, no change in molecular weight.</p> <p>24 Q. Okay. Now, here, different from</p> <p>25 Carolyn Lewis, you find that "the differential</p>	<p>1 something like that.</p> <p>2 Q. Last sentence of the last paragraph</p> <p>3 before you get to the table of contents, "It was</p> <p>4 found that the explant sample showed</p> <p>5 significantly less signal for the antioxidants</p> <p>6 as compared to the control sample, under 2</p> <p>7 percent for Santonox R and dilauryl</p> <p>8 thiodipropionate."</p> <p>9 A. That's right.</p> <p>10 Q. What does that mean?</p> <p>11 A. That means that 98 percent of it was</p> <p>12 gone.</p> <p>13 Q. Got it.</p> <p>14 A. This time we know for a fact, because</p> <p>15 the surgery was just performed, that it wasn't</p> <p>16 sitting in Steelgate for months.</p> <p>17 Q. Okay.</p> <p>18 A. Because it was -- the surgery was</p> <p>19 performed, and it was immediately forwarded to</p> <p>20 us as rapidly as possible. So it would have</p> <p>21 just been a matter of days at room temperature</p> <p>22 before we got it and could start our work, as</p> <p>23 opposed to I really didn't know how long the</p> <p>24 other ones, other samples had been at Steelgate</p> <p>25 when we started that, but here it has to be</p>

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<p>1 short.</p> <p>2 Q. Do you know the percentage of</p> <p>3 formaldehyde in which the material was stored?</p> <p>4 A. I do not.</p> <p>5 Q. Did you follow the same sample</p> <p>6 preparation methods we've described?</p> <p>7 A. Yes, in terms of removal of tissue and</p> <p>8 using forceps and disposable --</p> <p>9 Q. Why did you choose the control samples</p> <p>10 that you did in Table 1 on Page 6? Is that the</p> <p>11 same ones that you chose before?</p> <p>12 A. Same ones, yes.</p> <p>13 Q. The reason why I asked is because</p> <p>14 Table 1 on Page 13 shows a number of additional</p> <p>15 tests being conducted on the other controls.</p> <p>16 A. On page what?</p> <p>17 Q. Right here. Compare this chart to</p> <p>18 this chart. They should be the same, shouldn't</p> <p>19 they?</p> <p>20 MR. ANDERSON: Yes, they are.</p> <p>21 MR. THOMAS: Right here. All this</p> <p>22 data is not on this chart.</p> <p>23 MR. ANDERSON: Oh, the data, I thought</p> <p>24 you said the tests that were run.</p> <p>25 A. They weren't. That means that these</p>	<p>1 Q. And the others would be reflected in</p> <p>2 the lab notebooks?</p> <p>3 A. Lab notebooks.</p> <p>4 Q. And billings?</p> <p>5 A. Billings.</p> <p>6 Q. Do you know the answer to the question</p> <p>7 about why Page 6 shows in Table 1 the control</p> <p>8 sample analysis chart is different than it is in</p> <p>9 Carolyn Lewis which appears on Page 13?</p> <p>10 A. I'd have to refer to the lab</p> <p>11 notebooks. Maybe it's in the lab notebooks. Do</p> <p>12 you want me to do that?</p> <p>13 Q. Well, to the extent that there's other</p> <p>14 testing -- well, strike that. We'll come back</p> <p>15 to that.</p> <p>16 Look at your lab notebooks and see if</p> <p>17 you did new testing.</p> <p>18 A. Let's see. That would have had to</p> <p>19 have been --</p> <p>20 MR. ANDERSON: That's the old ones.</p> <p>21 (Witness reviewing documents.)</p> <p>22 A. 10/29.</p> <p>23 MR. ANDERSON: Here you go. This is</p> <p>24 Batiste.</p> <p>25 A. Scalpel -- yeah, that's Batiste.</p>
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<p>1 were run again. And the rest of these were not</p> <p>2 run again.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. So --</p> <p>5 A. We did another FTIR micro, we did</p> <p>6 another DSC, another GPCT.</p> <p>7 Q. Does this mean you repeated the test</p> <p>8 for the first two categories, the OM and the</p> <p>9 SEM?</p> <p>10 A. I need to see the billing.</p> <p>11 Q. How much of this testing did you do</p> <p>12 yourself; any of it?</p> <p>13 A. I don't -- these days I don't do much</p> <p>14 myself. I just supervise the lab personnel.</p> <p>15 Q. Is it fair to understand that for both</p> <p>16 Linda Batiste and Carolyn Lewis that others did</p> <p>17 the work for you and reported to you and</p> <p>18 prepared your report, and you're testifying</p> <p>19 based on other --</p> <p>20 A. I prepared the report. They gave me</p> <p>21 their individual results.</p> <p>22 Q. Okay. And you are preparing the</p> <p>23 report and testifying based on the work of</p> <p>24 others?</p> <p>25 A. Correct.</p>	<p>1 MR. ANDERSON: You're looking to see</p> <p>2 about the OM and SEM, I think.</p> <p>3 MR. THOMAS: The reason why the</p> <p>4 difference of charts.</p> <p>5 MR. ANDERSON: Yes.</p> <p>6 (Witness reviewing documents.)</p> <p>7 A. So this is all Batiste. There's no</p> <p>8 indication of any reruns of those standards, of</p> <p>9 the controls in here, so...</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Is it just an omission?</p> <p>12 A. I think it may just be an omission.</p> <p>13 Q. Okay.</p> <p>14 A. 3422128.</p> <p>15 Yeah, I think X is up here, that's</p> <p>16 correct. I think it's an omission. We'll have</p> <p>17 to correct the table.</p> <p>18 Q. Okay.</p> <p>19 A. It would have been the same data.</p> <p>20 Q. Do you remember, given that this</p> <p>21 report is dated today --</p> <p>22 A. I'll tell you what we can do. We can</p> <p>23 pick a control sample here and just see if the</p> <p>24 picture is identical.</p> <p>25 Q. Okay.</p>

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<p>1 A. That will be a good indication.</p> <p>2 I'm sorry, can we go off the record a</p> <p>3 second?</p> <p>4 MR. ANDERSON: We don't have to go off</p> <p>5 the record. Just don't talk while you're</p> <p>6 looking.</p> <p>7 (Witness reviewing document.)</p> <p>8 A. That picture looks identical, Figure 4</p> <p>9 looks identical to Figure 5 here, which is the</p> <p>10 same control.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Just for the record, you're referring</p> <p>13 to Exhibit Number 1, Page 20, Figure 4, to</p> <p>14 Exhibit Number 2, Page 12, Figure 5?</p> <p>15 A. Right.</p> <p>16 Q. So it's your best judgment, based upon</p> <p>17 your review of those documents, that you're</p> <p>18 using the same control information for both</p> <p>19 studies?</p> <p>20 A. Here would be a more definitive</p> <p>21 picture.</p> <p>22 MR. ANDERSON: Just answer his</p> <p>23 question.</p> <p>24 A. I'm sorry.</p> <p>25 BY MR. THOMAS:</p>	<p>1 now -- any findings different for Linda Batiste</p> <p>2 about your observations of the mesh?</p> <p>3 A. Anything different?</p> <p>4 Q. From what you found with Carolyn</p> <p>5 Lewis.</p> <p>6 A. Oh, sure, we've already specified one</p> <p>7 difference. The DSC didn't show --</p> <p>8 Q. That was a bad question.</p> <p>9 A. -- the decreased Delta H.</p> <p>10 Q. Let me start over again. Strike that.</p> <p>11 I better do it the right way.</p> <p>12 Let's go to Page 8 -- excuse me. I'm</p> <p>13 sorry. Page 14, Figure 8.</p> <p>14 In a number of places in Exhibits 1</p> <p>15 and 2 there will be figures with numbers that</p> <p>16 are shown on there. Here on Figure 8 there's</p> <p>17 Figures 1, 2, 3 and 4 in red on the mesh.</p> <p>18 Do these represent places where, what,</p> <p>19 scanning electron microscopy was conducted, or</p> <p>20 do you know?</p> <p>21 A. I don't know.</p> <p>22 Q. So like on the next page, on Page 15,</p> <p>23 Figure 10, there are red numbers 1, 2, 3, 4. Do</p> <p>24 you know what those represent?</p> <p>25 A. Well, I can look at the EDX and see if</p>
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<p>1 Q. So it's your best judgment, based upon</p> <p>2 your review of those documents, you're using the</p> <p>3 same control information for both studies?</p> <p>4 A. It looks that way. 159, you see --</p> <p>5 MR. ANDERSON: Do you feel like you've</p> <p>6 answered his question that you're using the same</p> <p>7 controls?</p> <p>8 THE WITNESS: Yes.</p> <p>9 MR. ANDERSON: Okay. Then we'll move</p> <p>10 on to the next one.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Now if you go to Page 9, Page 9,</p> <p>13 Figure 3, does this depict the Batiste mesh as</p> <p>14 first received by you and then separated into</p> <p>15 tissue and mesh as you did with the mesh in</p> <p>16 Carolyn Lewis?</p> <p>17 A. It does.</p> <p>18 Q. And did you follow the same</p> <p>19 procedures?</p> <p>20 A. We did.</p> <p>21 Q. And did Mr. --</p> <p>22 A. Adi Kulcarni. Yes, I watched him do</p> <p>23 it.</p> <p>24 Q. Okay. Do you recall making any</p> <p>25 findings different -- I'm up to Page 11 right</p>	<p>1 the numbers -- if we have four sites on EDX,</p> <p>2 that would be the likely -- if there's going to</p> <p>3 be any correlation, that's what it would be, go</p> <p>4 find this sample number.</p> <p>5 Q. When you say "EDX," the data that you</p> <p>6 have in your EDX analysis?</p> <p>7 A. Yeah. But I don't know, with a</p> <p>8 control like this, I don't know why that would</p> <p>9 -- it would make no sense, so I doubt it. But</p> <p>10 we can check one sample.</p> <p>11 Q. Check to make sure.</p> <p>12 A. 13161.</p> <p>13 It's not here. I don't know what it</p> <p>14 means.</p> <p>15 Q. Okay. And just so we're clear, if you</p> <p>16 go back to Carolyn Lewis, let's go to Page 24 of</p> <p>17 Carolyn Lewis. Figure 11, again samples 13162,</p> <p>18 and there are numbers in red, 1, 2, 3, 4, do you</p> <p>19 know what those represent?</p> <p>20 A. No, I do not.</p> <p>21 Q. Okay. If you go to Page 18, please,</p> <p>22 of Batiste, Exhibit 2, Figure 16. Is this the</p> <p>23 photograph -- strike that.</p> <p>24 What is that? What is Figure 16?</p> <p>25 A. That's an optical micrograph.</p>

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<p>1 Q. What is that?</p> <p>2 A. Photograph of not the SEM, but just a</p> <p>3 regular optical microscope of the fiber mesh</p> <p>4 with tissue imbedded in it.</p> <p>5 Q. And what is Figure 17?</p> <p>6 A. That's a low amplification SEM.</p> <p>7 Q. Of the same thing that's depicted in</p> <p>8 Figure --</p> <p>9 A. Right.</p> <p>10 Q. Excuse me.</p> <p>11 Is what's depicted in Figure 17 the</p> <p>12 same thing that's depicted in Figure 16, just by</p> <p>13 different medium?</p> <p>14 A. By different methods.</p> <p>15 Q. Methods.</p> <p>16 A. SEM versus optical.</p> <p>17 Q. And as you look at Figure 22 on</p> <p>18 Page 21, and Figure 23, how would you describe</p> <p>19 what you see in Figure 22?</p> <p>20 A. It looks like greatly cracked material</p> <p>21 where some of the material has actually flaked</p> <p>22 off, getting clear under regions underneath.</p> <p>23 Q. In your cast of characters -- excuse</p> <p>24 me.</p> <p>25 In your description that you used in</p>	<p>1 show you that one a while ago in the other set</p> <p>2 where the material was correlated with that</p> <p>3 large antioxidant level. Was it 411, 411 or</p> <p>4 something like that?</p> <p>5 Q. That's exactly right.</p> <p>6 A. I think it was 411. Yes, 411. That's</p> <p>7 minimally.</p> <p>8 Q. What page is that?</p> <p>9 A. 37.</p> <p>10 Q. That's in Exhibit 1.</p> <p>11 And that's your visual observations,</p> <p>12 you conclude that the cracking shown on Page 37</p> <p>13 in Figure 38, sample 13411, is minimal cracking;</p> <p>14 fair?</p> <p>15 A. Fair.</p> <p>16 Q. All right. What is moderately</p> <p>17 cracked?</p> <p>18 A. That might be moderate right there</p> <p>19 (indicating).</p> <p>20 Q. What page?</p> <p>21 A. 38.</p> <p>22 Q. Page 38. Are we in Exhibit 1?</p> <p>23 A. These are arbitrary categories, of</p> <p>24 course, that's why it's very difficult to put</p> <p>25 absolute numbers on these. But that certainly</p>
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<p>1 Exhibit Number 1 as not cracked, moderately</p> <p>2 cracked, or cracked, where does this fit?</p> <p>3 A. These photos here I would call</p> <p>4 severely cracked.</p> <p>5 Q. Considerably cracked?</p> <p>6 A. Considerably or severely, you could</p> <p>7 use either word.</p> <p>8 Q. Okay. Let me ask this question.</p> <p>9 You've used a number of different ways</p> <p>10 today to characterize the cracking that you've</p> <p>11 seen, and you've broken them down into</p> <p>12 categories in different places in your report.</p> <p>13 What categories of cracking do you</p> <p>14 deem to be relevant to your analysis on a</p> <p>15 comparative basis across these mesh?</p> <p>16 MR. ANDERSON: Objection. Asked and</p> <p>17 answered way long ago.</p> <p>18 But answer the question again.</p> <p>19 A. Minimally, not cracked, minimally,</p> <p>20 moderately, and then major cracking, or</p> <p>21 extensive cracking.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. What qualifies -- how would you</p> <p>24 describe something that's minimally cracked?</p> <p>25 A. Where I just would see like -- I did</p>	<p>1 is cracked more than the 411 sample.</p> <p>2 Q. So on Page 38, sample 13412, you</p> <p>3 describe as being moderately cracked.</p> <p>4 What is it about Exhibit 40 on Page 38</p> <p>5 of Exhibit Number 1 that qualifies that as</p> <p>6 moderately cracked?</p> <p>7 A. Particularly on the right side of the</p> <p>8 picture, the cracks are somewhat weak looking,</p> <p>9 they're not deep into the sample.</p> <p>10 Now, there are a couple of places</p> <p>11 there, this is what makes this so difficult,</p> <p>12 there are a couple of places on the left side</p> <p>13 where I would call it certainly more severe</p> <p>14 cracking, what they're not -- they don't</p> <p>15 represent a large portion of the surface.</p> <p>16 Q. So the cracks that you're referring to</p> <p>17 are less than a micron in width?</p> <p>18 A. Scale is 100-micron, yes, in that</p> <p>19 order.</p> <p>20 Q. And for Ms. Batiste on Page 21,</p> <p>21 Figures 21 and 23, how would you describe that</p> <p>22 cracking?</p> <p>23 A. Page what now?</p> <p>24 Q. 21.</p> <p>25 A. Well, you have to look at several of</p>

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<p>1 these photos taken together to get kind of like</p> <p>2 an average.</p> <p>3 Q. Okay.</p> <p>4 A. If I look at -- if I look at Page 20,</p> <p>5 I might call it moderate. But if I look at</p> <p>6 Page 21, these are different regions of the same</p> <p>7 sample, I'm going to call that severe, because</p> <p>8 of flaking.</p> <p>9 Q. Is it the flaking that makes it</p> <p>10 severe?</p> <p>11 A. Flaking, yeah, because the actual</p> <p>12 polymer is degraded so badly it's coming off the</p> <p>13 surface.</p> <p>14 Q. All right.</p> <p>15 A. It's also the depth. If you want to</p> <p>16 see the depth, Page 23 shows you the deep</p> <p>17 cracking that hasn't yet flaked, but you can see</p> <p>18 it's just dying to flake off on Page 23.</p> <p>19 Q. Just so the record is clear, that's a</p> <p>20 higher magnification than the early ones? It's</p> <p>21 450 times, right? Page 23 is 400 times, is that</p> <p>22 right?</p> <p>23 A. Yeah. So I would call this moderate</p> <p>24 to severe.</p> <p>25 Q. And is it the number of cracks?</p>	<p>1 A. Somewhat.</p> <p>2 Q. And that's for severe cracking?</p> <p>3 A. Well, it's severe. If I just saw one</p> <p>4 of those cracks and nothing else and it was</p> <p>5 clean everywhere else, like if all I saw was</p> <p>6 this --</p> <p>7 Q. What you're doing now is you're --</p> <p>8 A. I'm covering up the cracks. But I'm</p> <p>9 showing you the rest of the fiber. In this case</p> <p>10 the whole fiber isn't damaged, just the left</p> <p>11 side.</p> <p>12 Q. That's Figure 26?</p> <p>13 A. 22 -- Figure 25, sorry.</p> <p>14 Q. Figure 25 on Page 22 of Exhibit 2?</p> <p>15 A. Correct.</p> <p>16 Q. Okay. Figure 25 on Page 22 of</p> <p>17 Exhibit 2, the cracks that you see on the left</p> <p>18 side, again are 1 to 3 microns wide. That's 600</p> <p>19 times magnification, that's even higher?</p> <p>20 A. But you've got the scale here of --</p> <p>21 Q. You changed the page again on me.</p> <p>22 Which one are you looking at now?</p> <p>23 A. Page 23, 26.</p> <p>24 Q. Okay. Figure --</p> <p>25 A. 450X.</p>
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<p>1 A. Number of cracks, the depth of the</p> <p>2 cracks, and whether or not it's flaked all enter</p> <p>3 into the -- flaking tends to --</p> <p>4 Q. How are you able to measure the depth</p> <p>5 of the cracks? Or is this just by total</p> <p>6 eyeballing it?</p> <p>7 A. It's total eyeballing at this point,</p> <p>8 because you can't really -- until you see the</p> <p>9 pieces come off, and then they look like they're</p> <p>10 several microns.</p> <p>11 Q. As a practical matter, isn't it</p> <p>12 impossible to measure the depths of these cracks</p> <p>13 because they're so small?</p> <p>14 A. Well, to get an accurate measurement,</p> <p>15 right, looking at this photograph I can't tell</p> <p>16 you exactly how many. But the depth is at least</p> <p>17 as great, it would appear here, as the width.</p> <p>18 Q. So a little less than a micron?</p> <p>19 A. Well, I would say that's more like 2</p> <p>20 microns, that crack.</p> <p>21 Q. Okay.</p> <p>22 A. Some of -- this one might be 2 to 3,</p> <p>23 some of them are 1. They're variable.</p> <p>24 Q. Okay. And you would expect a similar</p> <p>25 depth to that 1 to 3 microns?</p>	<p>1 Q. Page 23, 450X, Figure 26.</p> <p>2 A. So that crack there on the -- the big</p> <p>3 crack in the middle of the left side of that</p> <p>4 picture looking at the scale has got to be on</p> <p>5 the order of --</p> <p>6 Q. 5 microns?</p> <p>7 A. -- 5-micron, something like that.</p> <p>8 Q. No way to tell from this how deep it</p> <p>9 is?</p> <p>10 A. You can tell from the -- now you can</p> <p>11 tell because it's bent upwards. The actual</p> <p>12 thickness of the polypropylene piece that's</p> <p>13 about to break off looks like it's 1 to</p> <p>14 2 microns.</p> <p>15 Q. Okay. But the depth there is not</p> <p>16 going to be any more than five microns?</p> <p>17 A. No.</p> <p>18 Q. Probably less?</p> <p>19 A. On that order, yes.</p> <p>20 Q. Okay. So that's severe cracking?</p> <p>21 A. Yes, because it runs, covers the</p> <p>22 entire --</p> <p>23 Q. Okay. Let's go to Page 29, Figure 33.</p> <p>24 You're conducting the SEM-EDX analysis</p> <p>25 here, correct?</p>

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<p>1 A. Yes. Correct.</p> <p>2 Q. And how would you describe the</p> <p>3 cracking that you see in Figure 33?</p> <p>4 A. Moderate in that particular piece.</p> <p>5 Q. All right. And Spectrum 2 and</p> <p>6 Spectrum 3 are shown.</p> <p>7 Is there a Spectrum 1?</p> <p>8 A. No. Usually just shows two pieces, I</p> <p>9 don't know why we had three on here.</p> <p>10 Q. Do you usually start numbering at 2?</p> <p>11 A. I don't know why that was done. It's</p> <p>12 2, he may have had a 1 somewhere else, or just</p> <p>13 didn't renumber them.</p> <p>14 Q. If there's a 1, it doesn't show up on</p> <p>15 the data that appears here, correct?</p> <p>16 A. Right. The box and the number</p> <p>17 correlates with the spectrum you see below.</p> <p>18 Q. Right.</p> <p>19 What's the difference between 34 and</p> <p>20 35?</p> <p>21 A. Just a scale-up.</p> <p>22 Q. Okay.</p> <p>23 A. So we can see the minor elements</p> <p>24 better.</p> <p>25 Q. I see.</p>	<p>1 this peak here, that's in the region that isn't</p> <p>2 cracked.</p> <p>3 Q. My question is not what the proof of</p> <p>4 it is. My question is what caused it.</p> <p>5 What caused the oxidation?</p> <p>6 A. What caused the oxidation. Well, that</p> <p>7 would probably be due to the inflammation, among</p> <p>8 other things, that's in the human body. If the</p> <p>9 material isn't protected by antioxidants and</p> <p>10 it's exposed to macrophages and hydrogen</p> <p>11 peroxide and so on, if there was inflammation,</p> <p>12 and shards were coming off the particle and</p> <p>13 inflammation is caused to increase that --</p> <p>14 Q. Are you guessing, or is that your</p> <p>15 opinion?</p> <p>16 A. That's published literature.</p> <p>17 Q. It's your opinion that published</p> <p>18 literature stands for the proposition that in</p> <p>19 the face of inflammation, that polypropylene</p> <p>20 mesh without antioxidants will degrade?</p> <p>21 A. Yes.</p> <p>22 Q. And what literature is that?</p> <p>23 A. Well, it goes back to --</p> <p>24 Q. Is that the Liebert article?</p> <p>25 A. Liebert article, it goes back to</p>
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<p>1 DSC, we decided there was no change,</p> <p>2 so there's no evidence of environmental stress</p> <p>3 cracking?</p> <p>4 A. Let me just look at the numbers, but I</p> <p>5 believe that's correct.</p> <p>6 (Witness reviewing document.)</p> <p>7 A. That's correct.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. So any oxidation that's occurring --</p> <p>10 strike that.</p> <p>11 So any of the cracks that we see in</p> <p>12 Linda Batiste is going to be due to straight</p> <p>13 oxidation?</p> <p>14 A. I believe that's correct.</p> <p>15 Q. And do you know what caused the</p> <p>16 oxidation in Linda Batiste's mesh?</p> <p>17 A. Well, one cause would be the lack of</p> <p>18 antioxidant in the fiber, if we find that, which</p> <p>19 we have to go look at the LCMS analysis</p> <p>20 primarily.</p> <p>21 The other would be the IR results for</p> <p>22 carbonyls to see if we had oxidation there.</p> <p>23 Those are the two primary -- well, and</p> <p>24 the third is the one I just showed you was EDX.</p> <p>25 Because that oxygen in the clean regions by EDX,</p>	<p>1 Oswald and Turi article, as early as '65.</p> <p>2 Q. Okay.</p> <p>3 A. Williams talks about it in a number of</p> <p>4 articles.</p> <p>5 Q. It's ultimately premised on the</p> <p>6 suggestion that the antioxidants in the Ethicon</p> <p>7 mesh have leached out and are gone, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Right.</p> <p>10 And it's only if the antioxidants are</p> <p>11 leached out and gone that your theory is</p> <p>12 correct?</p> <p>13 A. I don't know that it would mean you</p> <p>14 couldn't oxidize polypropylene even in the</p> <p>15 presence of antioxidants. You certainly can.</p> <p>16 But it retards it.</p> <p>17 Q. But you've not studied that question.</p> <p>18 Your theory and opinion is that the antioxidants</p> <p>19 have leached out, therefore the mesh is</p> <p>20 degraded? That's your opinion to a reasonable</p> <p>21 degree of certainty?</p> <p>22 A. It would be a fact in my mind, because</p> <p>23 we're looking at the actual lack thereof.</p> <p>24 Q. Okay.</p> <p>25 A. Not assuming lack of, I'm looking to</p>

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<p>1 see if we see a lack of.</p> <p>2 Q. I understand.</p> <p>3 But that's your opinion to a</p> <p>4 reasonable degree of scientific certainty how</p> <p>5 this degradation occurred; that is, that the</p> <p>6 antioxidants leached out leaving the mesh</p> <p>7 defenseless, and that is the reason why the mesh</p> <p>8 degraded?</p> <p>9 A. Yes.</p> <p>10 Q. Page 34 --</p> <p>11 A. Yes, sir.</p> <p>12 Q. -- on Exhibit 2.</p> <p>13 This same value is in Exhibit 1, the</p> <p>14 typical value for the melt point of</p> <p>15 polypropylene?</p> <p>16 A. Where are you?</p> <p>17 Q. I'm right in the middle of the page on</p> <p>18 Page 34.</p> <p>19 A. 34. Okay. Right.</p> <p>20 Q. Is it your opinion that the typical</p> <p>21 value for polypropylene melting is 175 degrees</p> <p>22 C?</p> <p>23 A. Again, that comes out of the book we</p> <p>24 looked at earlier this morning, Turi.</p> <p>25 Q. Do you know whether that is the</p>	<p>1 paragraph, "After you don't find a difference in</p> <p>2 molecular weight, the environmental stress</p> <p>3 cracking mechanism does not require a decrease</p> <p>4 in molecular weight."</p> <p>5 I think we've already decided that the</p> <p>6 mesh -- any mesh degradation for Ms. Batiste is</p> <p>7 not due to environmental stress cracking; fair?</p> <p>8 A. Right.</p> <p>9 Q. Okay.</p> <p>10 A. So that's why I state we observed</p> <p>11 cracking in the explant samples due to oxidation</p> <p>12 in the fiber surface, in this particular sample.</p> <p>13 Q. In the PYMS analysis on Page 34.</p> <p>14 A. Page 34?</p> <p>15 Q. I'm sorry, 44. Thank you.</p> <p>16 A. Okay.</p> <p>17 Q. Am I correct that there's no analysis</p> <p>18 of the Santonox antioxidant?</p> <p>19 A. Right.</p> <p>20 Q. Why not?</p> <p>21 A. As I mentioned this morning, in PYMS</p> <p>22 when you -- if you'll look at Page 45, Figure</p> <p>23 46, the antioxidants, you'll see a large --</p> <p>24 you'll see the control is the blue, and you'll</p> <p>25 see a large red peak righter blue is eluting.</p>
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<p>1 typical melt point for the polypropylene mesh</p> <p>2 that Ethicon manufactured and sold?</p> <p>3 A. No. We measured, we measured that as</p> <p>4 well. That's the controls. It's 165-ish.</p> <p>5 Q. Okay. My point is; you're not</p> <p>6 suggesting because it's 165 instead of 175 from</p> <p>7 the literature that it's more susceptible to</p> <p>8 environmental stress cracking or degradation,</p> <p>9 are you?</p> <p>10 A. I'm suggesting it's less crystalline.</p> <p>11 Q. Okay. Are you suggesting it's more</p> <p>12 susceptible to environmental stress cracking</p> <p>13 because --</p> <p>14 A. Than the native pellet polypropylene</p> <p>15 from which the fiber was manufactured, yes, I</p> <p>16 am.</p> <p>17 Q. And are you suggesting that it's more</p> <p>18 susceptible to oxidation because its melting</p> <p>19 point is 165 as opposed to 175 and 80</p> <p>20 polypropylene pellets?</p> <p>21 A. Yes.</p> <p>22 Q. Page 43 in your molecular weight</p> <p>23 analysis.</p> <p>24 A. Okay.</p> <p>25 Q. It says in the middle of the</p>	<p>1 What that is mostly is polypropylene fragment</p> <p>2 ions, and it was overwhelming the signal for</p> <p>3 Santonox R, so we really couldn't get an</p> <p>4 accurate reading.</p> <p>5 Q. Tell me what that means. I don't know</p> <p>6 how that works. I don't understand.</p> <p>7 A. Well, in LCMS you extract the</p> <p>8 additives, and then you shoot a solution of the</p> <p>9 extract, so you don't have the polymer to worry</p> <p>10 about at all.</p> <p>11 In PYMS you put the entire sample in,</p> <p>12 the solid polypropylene piece, or a bit of</p> <p>13 actual fiber, and then you burn it basically,</p> <p>14 pyrolyze it, and then the pieces go into the GC</p> <p>15 system column and get separated. But there are</p> <p>16 sometimes hundreds of thousands of pieces, and</p> <p>17 sometimes for materials you want to analyze they</p> <p>18 just get overwhelmed, the material I want to</p> <p>19 analyze for is overwhelmed by the background is</p> <p>20 what it's called.</p> <p>21 So any estimate we would have made</p> <p>22 here, we would have got a large peak, it doesn't</p> <p>23 mean anything because it's got all these other</p> <p>24 ions in it, which just is flooding the system in</p> <p>25 that particular time point.</p>

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<p>1 Now, for the other antioxidant, the</p> <p>2 lauryl thiodipropionate --</p> <p>3 Q. Let me just interrupt for a minute.</p> <p>4 Could you have changed your test or</p> <p>5 changed your materials to test again for</p> <p>6 Santonox in an effort to capture the</p> <p>7 concentration of Santonox?</p> <p>8 A. You can run single ion, extracted ion</p> <p>9 chromatography, we call it, that helps. In this</p> <p>10 case it didn't help enough.</p> <p>11 Q. Why does it work in the Carolyn Lewis</p> <p>12 case for all the samples that you've tested</p> <p>13 there, but doesn't for Linda Batiste?</p> <p>14 A. Don't have an answer for that. I just</p> <p>15 know this is characteristic of PYMS. LCMS gives</p> <p>16 -- in this case because we don't have the</p> <p>17 background, we don't have the degree of</p> <p>18 problems.</p> <p>19 Q. Just so I understand --</p> <p>20 A. It doesn't always not work either,</p> <p>21 it's a matter of a judgment call.</p> <p>22 Q. But you got PYMS testing and results</p> <p>23 in all but four of the samples you tested in</p> <p>24 Exhibit 1, correct? That's on Page 15 and 16.</p> <p>25 A. Oh, Exhibit 1?</p>	<p>1 Q. All right. At this time for the LCMS</p> <p>2 test beginning on Page 46, there's no formalin</p> <p>3 control data, is there?</p> <p>4 A. No.</p> <p>5 Q. So the tests that you conducted in</p> <p>6 LCMS would not show the extent to which formalin</p> <p>7 may have confounded your findings?</p> <p>8 A. For the Santonox R, that would be</p> <p>9 true. But for the lauryl thiodipropionate, the</p> <p>10 standards we've already run clearly were not</p> <p>11 extracted by the formalin.</p> <p>12 Q. You didn't do a formalin control test</p> <p>13 for Linda Batiste to determine the extent to</p> <p>14 which formalin would impact your LCMS findings;</p> <p>15 true?</p> <p>16 A. Well, we did it, but it's in reference</p> <p>17 one. Remember we're going to use these data</p> <p>18 together. Because we already have two formalin</p> <p>19 controls in the -- what do you call -- the</p> <p>20 Exhibit 1.</p> <p>21 Q. Okay.</p> <p>22 A. So yes, we have controls of formalin.</p> <p>23 Q. So whatever --</p> <p>24 A. Page 92 --</p> <p>25 Q. -- whatever conclusions might be drawn</p>
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<p>1 Q. Yes.</p> <p>2 A. Well, I know that one thing that's</p> <p>3 happened since this work was done was a column</p> <p>4 had to be changed out.</p> <p>5 Q. What does that mean?</p> <p>6 A. Well, the column eventually goes, and</p> <p>7 we have to cycle it out. So another column</p> <p>8 is -- this is not the same column that was run</p> <p>9 for the prior samples. So the selectivity is</p> <p>10 slightly different. And I'm telling you that</p> <p>11 the -- I'm sure of this, that it's being buried</p> <p>12 under polypropylene fragments.</p> <p>13 Q. So are you telling me that the results</p> <p>14 that you've obtained in Exhibit Number 1 for the</p> <p>15 PYMS data are different from the results that</p> <p>16 you obtained for the Linda Batiste sample in</p> <p>17 Exhibit 2?</p> <p>18 A. It's a different column, so the</p> <p>19 selectivity is a little bit different.</p> <p>20 Quantitation of additives is much more difficult</p> <p>21 than PYMS than it is -- it's good for detection</p> <p>22 and confirming the presence of things, it's not</p> <p>23 good for quantitating anything.</p> <p>24 Q. LCMS --</p> <p>25 A. LCMS is much better, in general.</p>	<p>1 from the formalin control samples and their</p> <p>2 impact on the antioxidants that may have been</p> <p>3 present in the mesh apply equally to your</p> <p>4 findings for Linda Batiste?</p> <p>5 A. That's correct.</p> <p>6 Q. Now, the control sample that you</p> <p>7 choose here on Page 50 is 3422128, and that will</p> <p>8 be, again, from the controls on Page 96 of</p> <p>9 Exhibit 1, correct?</p> <p>10 A. Okay. What am I -- on Page 50?</p> <p>11 Q. On Page 50, Table 12.</p> <p>12 A. Okay. 3422128.</p> <p>13 Q. You show that Santonox quantitation,</p> <p>14 correct?</p> <p>15 A. In that table.</p> <p>16 Q. Why did you choose the 4,430,284</p> <p>17 figure as the control against which you compare</p> <p>18 Santonox?</p> <p>19 A. It's in the middle. Hang on, let me</p> <p>20 check this again.</p> <p>21 Q. I don't see that value in the controls</p> <p>22 on Page 96. It should be there, shouldn't it?</p> <p>23 A. 3422128.</p> <p>24 Q. That value is different, isn't it?</p> <p>25 A. Yes.</p>

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<p>1 Q. Do you know why that is?</p> <p>2 A. That would indicate to me that he</p> <p>3 reran the control. We extracted it.</p> <p>4 Q. I thought we decided a moment ago they</p> <p>5 didn't.</p> <p>6 A. Most of the tests they didn't. I can</p> <p>7 check that.</p> <p>8 Q. Okay. So what this says is that we</p> <p>9 have yet a third value for this --</p> <p>10 A. Standard.</p> <p>11 Q. -- control --</p> <p>12 A. Control.</p> <p>13 Q. -- test.</p> <p>14 Not standard, it's a control?</p> <p>15 A. Control.</p> <p>16 Q. So the value here of 4430284, you</p> <p>17 think is a new test of mesh tested with Carolyn</p> <p>18 Lewis?</p> <p>19 A. Correct.</p> <p>20 Q. As you sit here today, do you know any</p> <p>21 other new tests that were conducted for Linda</p> <p>22 Batiste in order to do -- on the controls that</p> <p>23 were used to compare the Linda Batiste mesh</p> <p>24 samples?</p> <p>25 A. Let's check the control in Table 11</p>	<p>1 Q. Would it be -- do you know why this</p> <p>2 new control testing was conducted for Linda</p> <p>3 Batiste?</p> <p>4 A. Well, the response of the detectors,</p> <p>5 the HPLC type, LCMS detectors can change over</p> <p>6 time, so it would just be good lab practice,</p> <p>7 since this was run at a different time from the</p> <p>8 other samples, to rule out any change that way.</p> <p>9 Whereas an SEM photograph is an SEM photograph,</p> <p>10 it wouldn't matter, so there would be no need to</p> <p>11 rerun those.</p> <p>12 Q. Tell me again what it means to change</p> <p>13 the column.</p> <p>14 A. Well, when you're doing</p> <p>15 chromatography, columns wear out, and you have</p> <p>16 to periodically change them. The peaks get</p> <p>17 broad, they get narrower, materials start to</p> <p>18 bleed into -- peaks start to bleed into one</p> <p>19 another, and it's just time to change the</p> <p>20 column. It's just normal -- what we call normal</p> <p>21 maintenance, like changing the oil in a car.</p> <p>22 Q. How do you determine when it's</p> <p>23 appropriate to change the column?</p> <p>24 A. You have standards that you run, and</p> <p>25 you look for resolution standards. And when the</p>
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<p>1 just to see. All right. Let's go back.</p> <p>2 34221228.</p> <p>3 Q. What page are you on, please?</p> <p>4 A. 92 and 49. It's the number of -- it's</p> <p>5 the same standard run for the lauryl</p> <p>6 thiodipropionate, but the number is different</p> <p>7 again. So it's certainly right on the same</p> <p>8 range, but it means it's rerun, same thing.</p> <p>9 Q. So the dilauryl has also been rerun?</p> <p>10 A. The standard has, yes, along with the</p> <p>11 actual sample.</p> <p>12 Q. Where are you looking to see that?</p> <p>13 A. Table 11, lot 3422128, Page 49.</p> <p>14 Q. And that's a value -- you have two of</p> <p>15 those values from the first one on Page 92, and</p> <p>16 on Page 92 of Exhibit Number 1 you obtained a</p> <p>17 value of 71,633,460?</p> <p>18 A. Mm-hmm.</p> <p>19 Q. And a duplicate result of 96,522,909,</p> <p>20 and this is a third value for the same piece of</p> <p>21 mesh at 82,091,505.</p> <p>22 A. Right, between the other two.</p> <p>23 Q. Okay. So do you know of any other new</p> <p>24 control testing conducted for Linda Batiste?</p> <p>25 A. I do not.</p>	<p>1 resolution no longer meets the minimum standard,</p> <p>2 it's time to change it. It's part of the SOP.</p> <p>3 Q. How often do you change the column?</p> <p>4 A. When? I don't know how to answer</p> <p>5 that.</p> <p>6 Q. Every 2,000 miles?</p> <p>7 A. It's when it fails, when it fails a</p> <p>8 test.</p> <p>9 Q. Okay.</p> <p>10 A. It's checked every time we run samples</p> <p>11 to see that the minimum resolution is there, or</p> <p>12 it's changed.</p> <p>13 Q. Before you sat down to give your</p> <p>14 deposition today, did you realize that the</p> <p>15 controls had had additional testing conducted on</p> <p>16 them?</p> <p>17 A. These controls here?</p> <p>18 Q. In Exhibit 2 for Linda Batiste.</p> <p>19 A. No. In all honesty, no.</p> <p>20 Q. Okay. Fair to understand that a</p> <p>21 doctor would have to give any opinion about the</p> <p>22 extent to which any degradation in the mesh that</p> <p>23 you have found would cause Ms. Batiste any</p> <p>24 physical harm or other health problems?</p> <p>25 A. No, I would defer to them for the</p>

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<p>1 actual physical type damage, it's not -- it's 2 beyond, out of my field. 3 MR. THOMAS: I'm going to want copies 4 of everything but the Burkley deposition. The 5 lab notebooks, the articles, and the SOPs. 6 MR. ANDERSON: Just leave them all 7 there for right now. 8 MR. THOMAS: What's the best way to do 9 that, Ben? 10 MR. ANDERSON: Good question. The lab 11 notebooks obviously can't leave, so we would 12 just have to run copies of those for you. All 13 the other things we can run copies for you. Or 14 we can give them to madame court reporter and 15 have her run some copies. 16 MR. THOMAS: I don't care just as long 17 as I get them. Whatever makes sense. I think 18 you and I can figure this out. 19 MR. ANDERSON: Okay. 20 BY MR. THOMAS: 21 Q. Doctor, you brought a number of things 22 with you to the deposition today including a 23 number of books, a copy of the deposition of Dan 24 Burkley. 25 I have here three laboratory</p>	<p>1 BY MR. THOMAS: 2 Q. Do you know whether all of the samples 3 were tested? 4 A. No. Some of the samples weren't 5 tested. 6 Q. Do you know why some weren't tested? 7 A. There were several that weren't, two 8 or three maybe that weren't tested because they 9 were mixtures of multiple products, and we 10 didn't want to run those. 11 Q. Okay. Is there any way to tell from 12 the entries in the lab notebook, to your 13 knowledge, about the reasons why certain ones 14 weren't tested? 15 A. Here's one that wasn't run and it 16 wasn't run because -- I'm assuming it wasn't run 17 because sample received with no formalin. We 18 didn't run it. We didn't know what would happen 19 to the sample in the absence of preservatives so 20 we just didn't run it. 21 Q. And who was that? 22 A. We have several here. Cynthia 23 Simpson, and Alma Sarcia. 24 MR. ANDERSON: Garcia. 25 A. Garcia. Sorry. JPG240-241,</p>
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<p>1 notebooks. What are these? 2 A. These are the laboratory notebooks 3 telling the sample preparation and what was done 4 to the samples, and by who, and on what date. 5 Q. What's the purpose of a laboratory 6 notebook? What are you trying to capture in a 7 laboratory notebook? 8 A. We're trying to capture when things 9 were done so that we know who did what so we can 10 go ask questions of proper people so we have a 11 paper trail for the way the sample was handled. 12 Q. Is it fair to understand one of the 13 goals of a lab notebook is to provide enough 14 information so that somebody coming behind you 15 can understand what you did and recreate it if 16 necessary? 17 A. Yes. Absolutely. 18 Q. And the lab notebook has a number of 19 names in here. Are these the people who's 20 samples were tested, do you know? 21 A. You'll have to show me the specifics. 22 (Witness reviewing document.) 23 A. Yes, those are the sample -- 24 MR. ANDERSON: Hand it back to him. 25 "Yes" answers the question.</p>	<p>1 JPG1362-1363. 2 BY MR. THOMAS: 3 Q. And did you have anything to do with 4 the decision not to test those products? 5 A. Well, it would be standard operating 6 procedure that if something comes in in a 7 non-standard format in a situation as -- well, 8 any situation, we wouldn't run it without the 9 client's approval. We'd have to go back to them 10 and see if they still wanted to run it, because 11 otherwise -- 12 Q. Did you, in fact, raise that issue 13 with anybody about whether the sample should be 14 tested because it did not come in formalin? 15 A. I think the analysts probably got 16 together and discussed it, yeah. 17 Q. Did you have any role in the 18 decision -- 19 A. No, I didn't. That's standard 20 operating procedure. 21 Q. Let me finish my question, please. 22 Did you ever any role in the decision 23 not to test the mesh samples that did not come 24 in formalin? 25 A. No.</p>

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<p>1 Q. Were you aware before reading the 2 laboratory notebook today during your deposition 3 that a decision was made not to test some of the 4 mesh samples because they didn't have formalin? 5 A. Yeah, we've discussed that. 6 Q. Who have you discussed it with? 7 A. Adi Kulcarni who has been involved in 8 this, and my son Mark. 9 Q. What did you discuss about that? 10 A. Just that we didn't feel it was fit to 11 run because they were different, they didn't 12 match normal composition. 13 Q. Why? They looked different? 14 A. They were dry, yeah. 15 Q. Okay. Do you know if they'd ever been 16 in formalin? 17 A. I assume they had, but I have no way 18 to know that. They're supposed to send them to 19 us in formalin, so you've got to assume they 20 were sent in formalin at some point. 21 Q. Okay. 22 A. And it was lost. We don't know when. 23 MR. ANDERSON: Don't assume things 24 that you don't know. If you know the answer, 25 then you say I know the answer.</p>	<p>1 A. Today he is, yes. 2 Q. Has he been for the last two years? 3 A. Yes. 4 Q. So any testing that would have come in 5 Jordi Labs to test polypropylene mesh would have 6 been overseen by your son Mark? Is that his 7 name? 8 A. Yes. 9 Q. To the extent that questions I asked 10 you before about other mesh that has been 11 analyzed by Jordi Labs, the person who would 12 know about that is your son Mark? 13 A. Yes. Not me. 14 Q. How long has it been since you've had 15 hands-on responsibility in the lab? 16 A. Four, five years now. 17 Q. And what do you do here at Jordi Labs? 18 A. I'm involved in R&amp;D. And I act as an 19 expert witness. I review jobs as requested. We 20 try to have three or four or five people review 21 every job that goes out to look for errors, that 22 kind of thing. I'm working in developing new 23 products. 24 Q. How much of your time is spent 25 consulting as an expert witness?</p>
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<p>1 THE WITNESS: I don't know the answer. 2 MR. ANDERSON: If you don't know the 3 answer, please say I don't know the answer, 4 okay? 5 BY MR. THOMAS: 6 Q. How many samples did you receive 7 without formalin that you didn't test? 8 (Witness reviewing document.) 9 A. Looks like two. 10 BY MR. THOMAS: 11 Q. And you identified one of them. 12 What's the other one? Can you identify that for 13 me, please? 14 MR. ANDERSON: He said both those 15 names. 16 A. I said both. 17 BY MR. THOMAS: 18 Q. I'm sorry. Thank you. 19 Who runs your lab? 20 A. My son and his business partner. 21 Q. What's his business partner's name? 22 A. Patrick Burke. 23 Q. Is he the person -- is your son the 24 person responsible for all testing conducted by 25 Jordi Labs?</p>	<p>1 A. Well, generally it's a sideline, this 2 case being a little bigger than most that we've 3 seen. 4 Q. In the last three months, how much of 5 your time has been occupied by this case? 6 A. Three months, probably 50 percent. 7 Q. Okay. What have you done the other 50 8 percent of the time? 9 A. Well, as I said, I'm reviewing jobs, 10 I'm working on developing new products, which 11 I've been doing for years. 12 Q. In the last two years, have you had 13 any responsibility for supervising the 14 activities in the lab? 15 A. In the last two years? 16 Q. Yes. 17 A. No. 18 Q. All right. And you rely on your son 19 to make sure that that goes off and the work 20 gets done as it needs to get done? 21 A. Right. 22 Q. Is Jordi Labs privately held? 23 A. Yes, it is. 24 Q. How many shareholders in Jordi Labs? 25 A. Two.</p>

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<p>1 Q. Who are they?</p> <p>2 A. My son and his business partner.</p> <p>3 Q. You no longer are an owner of Jordi</p> <p>4 Labs?</p> <p>5 A. No. My son. I wanted to get out in</p> <p>6 time from the ownership situation.</p> <p>7 Q. Okay. And when did that happen?</p> <p>8 A. I don't remember exactly. It's four</p> <p>9 or five years.</p> <p>10 Q. How many employees does Jordi Labs</p> <p>11 have now?</p> <p>12 A. Again, I don't know exactly. It</p> <p>13 changes every day. I'd say 25, 26, around</p> <p>14 there.</p> <p>15 Q. Do you know what percentage of the</p> <p>16 Jordi Labs work is legal consulting on legal</p> <p>17 cases?</p> <p>18 A. Well, generally it's a small</p> <p>19 percentage. As I say, right now it's a bigger</p> <p>20 percentage because of the nature of this case,</p> <p>21 but it's an unusual situation.</p> <p>22 Q. In this stack of documents are a</p> <p>23 number of reports from an Evans Analytical</p> <p>24 Group.</p> <p>25 A. Right.</p>	<p>1 Q. Do you specifically know how that</p> <p>2 happened?</p> <p>3 A. Not exactly, I don't.</p> <p>4 Q. Okay. That's fine.</p> <p>5 And what did you do to assure that</p> <p>6 Evans Analytical Group and -- what's the other</p> <p>7 company?</p> <p>8 MR. ANDERSON: They're both Evans.</p> <p>9 A. They're both Evans, different</p> <p>10 divisions.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Sorry. Strike that.</p> <p>13 What did you do to assure that the</p> <p>14 Evans Analytical Group was capable of performing</p> <p>15 the work that you asked them to do?</p> <p>16 A. We've been working with a gentleman at</p> <p>17 Chemir, and we've been referring jobs back and</p> <p>18 forth for years at various times, and he is --</p> <p>19 he's really our contact with Evans. We've had</p> <p>20 tremendous results for a number of years working</p> <p>21 with -- both ways, he sends a lot of work here,</p> <p>22 we send some -- we send a lot of work his way.</p> <p>23 Q. So the FTIR -- strike that.</p> <p>24 So all of the data done by Evans was</p> <p>25 added to your report without change or input</p>
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<p>1 Q. Tell me what those are, please.</p> <p>2 A. The FTIR microscope work was done by</p> <p>3 Evans in California, and the SEM, SEM-EDX was</p> <p>4 done by Evans Group in Minnesota.</p> <p>5 Q. Is that because you don't have the --</p> <p>6 A. We don't have those instruments.</p> <p>7 Q. How did you happen to choose the Evans</p> <p>8 Analytical Group to perform this testing?</p> <p>9 A. We've worked with a company called</p> <p>10 Chemir in the past, they were bought out by</p> <p>11 Evans, and they're, I think, about a \$7 billion</p> <p>12 company, and they're a very well respected lab,</p> <p>13 so we utilize their technique that we don't</p> <p>14 have.</p> <p>15 Q. Is it the FTIR data --</p> <p>16 A. FTIR microscope.</p> <p>17 Q. Okay. So for the FTIR and the</p> <p>18 scanning electron microscope work, you ship that</p> <p>19 out?</p> <p>20 A. That's correct.</p> <p>21 Q. And how did you transport the samples?</p> <p>22 A. They were sent by our office staff</p> <p>23 following the regulations that we -- procedures</p> <p>24 that were set up and described to us to handle</p> <p>25 and to keep chain of custody.</p>	<p>1 from you?</p> <p>2 A. Yes. Basically you have those</p> <p>3 results. Any changes you can see there. I'm</p> <p>4 sure there were a few verbal changes, but</p> <p>5 essentially it's the IR spectra, the IR spectra.</p> <p>6 We certainly wouldn't have -- we wouldn't even</p> <p>7 have the capability of changing those spectra.</p> <p>8 Q. Okay. Has Jordi Labs ever had an</p> <p>9 electron microscope?</p> <p>10 A. No.</p> <p>11 Q. Has Jordi Labs ever had the capability</p> <p>12 to do the FTIR analysis?</p> <p>13 A. Yes.</p> <p>14 Q. When did you have that?</p> <p>15 A. Oh, probably -- well, we've had it</p> <p>16 since basically day one of the company at</p> <p>17 various units. Classical FTIR. Now we have the</p> <p>18 Diamond ATR system.</p> <p>19 Q. You still have it?</p> <p>20 A. Absolutely.</p> <p>21 Q. Why do you ship this out to Evans?</p> <p>22 MR. ANDERSON: Micro.</p> <p>23 A. Micro.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. I'm sorry. Okay.</p>

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<p>1 Has Jordi ever had the capability to</p> <p>2 do the kind of work that Evans did on the FTIR?</p> <p>3 A. No, we have never had an FTIR</p> <p>4 microscope system.</p> <p>5 Q. Who is Scott Bowman?</p> <p>6 A. He's the gentlemen that transfers jobs</p> <p>7 back and between us and Evans, or he sends us</p> <p>8 work, we send him work.</p> <p>9 Q. Does he work for Jordi or work for</p> <p>10 Evans?</p> <p>11 A. He works for himself.</p> <p>12 Q. Pretty good gig.</p> <p>13 A. It's worked out extremely well for us</p> <p>14 and extremely well for him. We love his</p> <p>15 expertise and his ability to get us in touch</p> <p>16 with the best people.</p> <p>17 Q. He's not a -- is he a technical guy?</p> <p>18 A. Absolutely is.</p> <p>19 Q. Does he do any technical work?</p> <p>20 A. No, he just basically is --</p> <p>21 Q. He's a broker?</p> <p>22 A. He's a broker, a very good one.</p> <p>23 Q. So on these SEM analysis reports here</p> <p>24 that you got apparently from Evans --</p> <p>25 A. He may --</p>	<p>1 how to conduct the tests that you did?</p> <p>2 A. That's right.</p> <p>3 Q. Diamond Shamrock Corporation, is this</p> <p>4 a standard for polypropylene, or can you tell by</p> <p>5 looking at it?</p> <p>6 A. Let me take a look. I can't read it</p> <p>7 from there.</p> <p>8 Q. (Handing).</p> <p>9 A. Yes, that's the polypropylene standard</p> <p>10 spectrum. Isotactic.</p> <p>11 Q. When we talked before, I thought we</p> <p>12 decided you didn't use a standard against which</p> <p>13 to compare your results, that you used your own</p> <p>14 training, education, literature.</p> <p>15 A. There's no way for me to keep track of</p> <p>16 everything these people are doing out here now.</p> <p>17 I'm telling you the polystyrene is the one</p> <p>18 that's used.</p> <p>19 Q. Do you know the extent to which the</p> <p>20 people in the lab used that Diamond Shamrock</p> <p>21 standard for polypropylene in connection with</p> <p>22 their work on the opinions in Exhibit 1 or 2?</p> <p>23 Do you know?</p> <p>24 A. No, because these -- this isn't an SOP</p> <p>25 anyway. This is just a bunch of spectra. I'm</p>
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<p>1 MR. ANDERSON: Hold on.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. -- the numbers appear that I asked you</p> <p>4 about, you didn't know where they came from?</p> <p>5 A. Right.</p> <p>6 Q. Is it likely that the numbers that I</p> <p>7 asked you about in both reports on the SEM</p> <p>8 images, likely those were put on there by Evans,</p> <p>9 or do you know?</p> <p>10 A. They would have had to have been put</p> <p>11 on by Evans because we couldn't have done it.</p> <p>12 Q. Okay.</p> <p>13 A. It's their pictures.</p> <p>14 Q. Do you have these in an electronic</p> <p>15 format? I'm sure you do. Digital format?</p> <p>16 A. I'm sure we can get them. Adi, again,</p> <p>17 would know, handles that kind of thing for me.</p> <p>18 Q. Did you do all the other testing</p> <p>19 in-house?</p> <p>20 A. Yes, we did.</p> <p>21 Q. The documents that I'm going through</p> <p>22 now are Jordi SOPs, is that correct?</p> <p>23 A. Yes.</p> <p>24 Q. And these would be the internal</p> <p>25 procedures that you have that instruct folks in</p>	<p>1 not sure why that's even in there, it's not SOP.</p> <p>2 Q. Okay. Just for the record, it's a</p> <p>3 multi-page document copyrighted 1980, 1981, 1993</p> <p>4 for Sadtler, and it's Diamond Shamrock</p> <p>5 Polypropylene.</p> <p>6 What's the document I just gave you</p> <p>7 there, do you know? Do you recognize that?</p> <p>8 A. It's another polypropylene spectrum,</p> <p>9 J7904.</p> <p>10 Oh, let me see the other one again,</p> <p>11 please.</p> <p>12 Q. (Handing).</p> <p>13 (Witness reviewing document.)</p> <p>14 A. These appear to be spectra of the</p> <p>15 explants done on our instrument which were</p> <p>16 polypropylene. We saw lots of noise. This is</p> <p>17 why we chose to go with the FTIR microscope</p> <p>18 route. We had to look at the total samples,</p> <p>19 number one.</p> <p>20 Number two, the samples wouldn't lay</p> <p>21 flat on our Diamond, and they tended to want to</p> <p>22 bounce around because they were rigid, and so it</p> <p>23 was difficult to get a good spectrum, it was</p> <p>24 lots of noise, so we went to where we could go</p> <p>25 to a high sensitivity technique where we could,</p>

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<p>1 number one, hone in on the cracked regions.  2 When you run a sample with an instrument like  3 this, you're running can the total sample, so  4 you're diluting the effect on the cracked  5 regions, you'd be running a combination of  6 cracked and uncracked regions. When we use the  7 IR microscope, you can hone in on any specific  8 region of the fiber we want, that's the  9 advantage. So we decided to go with that  10 technique because it offered us -- for what we  11 needed for this work, it's a far better  12 methodology.  13 Q. Before I showed you these documents,  14 were you aware that Jordi Labs had tried to  15 analyze in-house --  16 A. Yes, I was.  17 Q. -- the FTIR spectra for these  18 explants?  19 A. Yes, I was.  20 Q. Okay. And you tried it, and the  21 documents you just looked at are the documents  22 that you generated in-house from your results of  23 your analysis, correct?  24 A. That's -- I'm sorry, go ahead, ask the  25 question again. I'm sorry.</p>	<p>1 can find out if those are extra copies. If  2 those are extra copies, she can take them with  3 her. If they're not, then we'd like to leave  4 them here so that we can make copies, or we can  5 have you take them and make copies. I think I  6 need to make sure they're not originals.  7 MR. THOMAS: Here's what I'd like to  8 have, you tell me if I can have it. I'd like to  9 have a hard copy and a digital copy.  10 MR. ANDERSON: Well, I'd like to have  11 a million bucks and retire tomorrow, so if you  12 can deliver I will.  13 MR. THOMAS: You can't retire on a  14 million dollars, I know you.  15 MR. ANDERSON: It will last me a  16 couple months.  17 MR. THOMAS: That wouldn't keep you in  18 Red Bull.  19 MR. ANDERSON: If you're getting  20 digital -- well, hopefully they have it in  21 digital, then we'll give it to madame court  22 reporter and it will be an exhibit to the depo.  23 If -- that will still be in digital for you, so  24 you need a hard copy. We'll do the best we can.  25 If it's digital --</p>
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<p>1 Q. I will mark as Exhibit Number 7 the  2 documents you've just been looking at.  3 (Whereupon, Jordi Exhibit Number 7,  4 Group of films, was marked for  5 identification.)  6 BY MR. THOMAS:  7 Q. And the first page is the Diamond  8 Shamrock standard from Sadtler, S-A-D-T-L-E-R,  9 and then attached to that are FTIR spectra that  10 you all ran in-house with your own capability,  11 at which point you determined that you weren't  12 generating the specificity of the data you  13 needed to make your analysis so you contracted  14 it out for microscopic FTIR?  15 A. That's correct.  16 Q. Is that fair?  17 A. That's fair.  18 Q. Mark that as Exhibit Number 7.  19 MR. THOMAS: I won't mark the lab  20 notebooks.  21 The rest of what I have here are  22 miscellaneous SOPs, the Evans reports, and the  23 Evans reports. Do you want the court reporter  24 to have those, or how do you want to do this?  25 MR. ANDERSON: What we can do is we</p>	<p>1 MR. THOMAS: Digital is my first  2 choice, I'll print my own copy. The hard copy  3 allows me to know I have everything. Not  4 because I'm suggesting you're going to do  5 anything with it.  6 MR. ANDERSON: No, it's easier. I'm a  7 hard copy guy, too. Why don't we figure that  8 out after the depo.  9 BY MR. THOMAS:  10 Q. I'd also like a color copy of your  11 studies that you have.  12 A. You'd like a what, sir?  13 Q. Color copy so I can capture the  14 highlighting in your studies. Because you  15 brought with you today a notebook of studies  16 upon which you rely for your opinions in the  17 case.  18 A. Articles, yes.  19 Q. And you have highlighting and writing  20 on them, correct?  21 A. Mostly highlighting, yes.  22 Q. I want versions of those that capture  23 the highlighting.  24 MR. ANDERSON: Absolutely.  25 A. Fair enough.</p>

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<p>1 MR. ANDERSON: We need to take a</p> <p>2 break. Let's take a break.</p> <p>3 (Whereupon, a recess was taken from</p> <p>4 4:39 p.m. to 4:56 p.m.)</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Doctor, attached to Exhibit 1 is a</p> <p>7 part of -- oh, right after your primary report,</p> <p>8 is your CV. I'm just going to ask you some</p> <p>9 questions about your career. You can look at</p> <p>10 the CV if you want to. I imagine you know it</p> <p>11 pretty well.</p> <p>12 A. Where is it here? What page?</p> <p>13 Q. It's after Page 102. I bet you it's</p> <p>14 in the back of that.</p> <p>15 A. Appendix. Conclusion.</p> <p>16 MR. ANDERSON: After Page 102?</p> <p>17 MR. THOMAS: That's where I have it.</p> <p>18 It will be in that copy right there.</p> <p>19 A. All right. That's fine.</p> <p>20 MR. THOMAS: We've got it here, Ben.</p> <p>21 A. Okay.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. All right. Tell me about your</p> <p>24 education after college, Dr. Jordi. I mean</p> <p>25 after high school.</p>	<p>1 Q. And your job as an analytical chemist</p> <p>2 was to do the lab work associated with any</p> <p>3 issues that might arise?</p> <p>4 A. Whatever came up. Whatever projects</p> <p>5 they wanted support for.</p> <p>6 Q. All right. And the extent to which</p> <p>7 any of these products may be appropriate for use</p> <p>8 in humans would be something beyond what you</p> <p>9 were doing in the lab on the bench?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. What did you do -- you were</p> <p>12 next employed for six months at Waters</p> <p>13 Associates. What were you have doing there;</p> <p>14 more of the same analytic chemist group?</p> <p>15 A. Basically Waters at that time was,</p> <p>16 still is a great company, but by my standards,</p> <p>17 my personality, I like a company that's</p> <p>18 personable with their customers. They had a</p> <p>19 philosophy at that time that they would work to</p> <p>20 solve the customer's separation need and earn</p> <p>21 the sale of the HPLC instrument through</p> <p>22 providing the solution of their separations</p> <p>23 problem, and so my job was to develop those</p> <p>24 methods. The sales rep would come in and say</p> <p>25 "this guy wants to separate such and such, and</p>
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<p>1 A. I went to Northern Illinois University</p> <p>2 in DeKalb, Illinois, worked on my bachelor's</p> <p>3 degree in chemistry, graduated in the summer of</p> <p>4 1967.</p> <p>5 Was offered a graduate position there,</p> <p>6 an NIH fellowship, so I stayed there and worked</p> <p>7 on my doctorate degree. I finished that in</p> <p>8 1973, and actually officially graduated in</p> <p>9 January of '74, but I'd already left and was</p> <p>10 already in the US Army at Walter Reed by that</p> <p>11 point.</p> <p>12 Q. You worked at Walter Reed for how many</p> <p>13 years?</p> <p>14 A. A little over three years.</p> <p>15 Q. What did you do at Walter Reed?</p> <p>16 A. It was a lab tech chemist position. I</p> <p>17 worked with, as I mentioned, the biodegradable</p> <p>18 implants, polylactic and glycolic acid</p> <p>19 copolymers. We had an another project for</p> <p>20 purification of eugenol, which is used by</p> <p>21 dentists. I worked on developing methods of</p> <p>22 purifying eugenol.</p> <p>23 Q. You were employed at this time as an</p> <p>24 analytical chemist?</p> <p>25 A. Basically.</p>	<p>1 get me a method so we can sell the instrument."</p> <p>2 Q. Okay.</p> <p>3 A. At that time liquid chromatography was</p> <p>4 nowhere near as advanced as it is now, so if a</p> <p>5 guy wanted to separate something, likely there</p> <p>6 was no published methods available many times,</p> <p>7 so then we would get involved.</p> <p>8 Q. So were your years -- or your time at</p> <p>9 Waters dealing primarily with liquid</p> <p>10 chromatography?</p> <p>11 A. Yes, or columns.</p> <p>12 Q. Or columns.</p> <p>13 Does that include your entire time at</p> <p>14 Waters up until February, 1980?</p> <p>15 A. Yes. Developed amino acid, worked on</p> <p>16 developing an amino acid analyzer, first</p> <p>17 generation amino acid analyzer. And then they</p> <p>18 sent me places to install amino acid analyzers,</p> <p>19 like they sent me to Germany, they sent me to</p> <p>20 Chicago.</p> <p>21 Q. Continuing in the analytical chemistry</p> <p>22 area?</p> <p>23 A. Yeah, it was amino acid analysis at</p> <p>24 this point, that was the specialty at that point</p> <p>25 in time. It always kept changing depending on</p>

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<p>1 the needs of the company, of course.</p> <p>2 Q. Then you went for a short time to LC</p> <p>3 Laboratories?</p> <p>4 A. I'm looking at the order of these</p> <p>5 pages here.</p> <p>6 Q. You go back to front, I think.</p> <p>7 A. There's Army. The pages aren't</p> <p>8 listed.</p> <p>9 MR. ANDERSON: Is this it here?</p> <p>10 A. Where are we here?</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Hopefully February, 1980 to September,</p> <p>13 1980, it looks like you were employed by LC</p> <p>14 Laboratories as a senior chemist?</p> <p>15 A. That's right.</p> <p>16 Q. You managed the complete polymer GPC</p> <p>17 program?</p> <p>18 A. Right. I was working at the time with</p> <p>19 a Waters 150C, which is a high temperature GPC</p> <p>20 system running high temperature samples, among</p> <p>21 other things, and I was responsible for</p> <p>22 maintaining that instrument.</p> <p>23 And we also were a contract lab, so we</p> <p>24 got all kinds of projects. Whatever the</p> <p>25 customers sent in they wanted us to do, we did,</p>	<p>1 Q. How would you describe the business of</p> <p>2 Jordi Labs today?</p> <p>3 A. We're an analytical testing lab,</p> <p>4 material science, some expert witness testimony,</p> <p>5 it's not the major thrust by any stretch,</p> <p>6 product development. Because the other side of</p> <p>7 the business that I developed during my time is</p> <p>8 several dozen products, fluorinated gel that I</p> <p>9 patented that's selling.</p> <p>10 Q. What does a fluorinated gel do?</p> <p>11 A. Well, in chromatography, as you run</p> <p>12 fast -- liquid chromatography, or any</p> <p>13 chromatography, as you run faster you'll tend to</p> <p>14 get less efficient plates. Plates is a</p> <p>15 narrowness of the peaks coming off, and the</p> <p>16 narrower they are the better, the more things</p> <p>17 separated the narrower they are.</p> <p>18 So with the fluorinated gel, solvents,</p> <p>19 it's like Teflon surface chemistry, solvents</p> <p>20 tend not to wet it. Since solvents don't wet</p> <p>21 surface, they don't create drag, and that's what</p> <p>22 broadens the peaks. And so now I can run</p> <p>23 something at 10 mils a minute instead of one mil</p> <p>24 a minute, I can run at one-tenth the time on</p> <p>25 that kind of column.</p>
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<p>1 just like we have here now.</p> <p>2 Q. Same kind of internal analytical work?</p> <p>3 A. Yes.</p> <p>4 Q. Okay.</p> <p>5 A. It might be prep, it might be</p> <p>6 developing analytical method, it might be</p> <p>7 polymer formulation, whatever, whatever it was.</p> <p>8 Q. And then from October of 1980 until</p> <p>9 July, 2008 you ran your own show?</p> <p>10 A. That's right. Remember I told you</p> <p>11 four or five years, that's where it is. 2008 we</p> <p>12 turned it over to Mark.</p> <p>13 Q. Has the business of Jordi Labs largely</p> <p>14 been the same over the time frame it's operated?</p> <p>15 A. Yes. But we're continuing to add</p> <p>16 instrumentation. So some of the instruments we</p> <p>17 don't have now, if you come back in a few years,</p> <p>18 lord willing, we will have. Like we're thinking</p> <p>19 about an FTIR microscope system, we're thinking</p> <p>20 about an SEM system. We just invested in a QTOF</p> <p>21 GC system which should be in within the next few</p> <p>22 months to match the LCMS QTOF system, which</p> <p>23 gives you more accurate mass and better ability</p> <p>24 to get more accurate mass and more accurate</p> <p>25 identification of unknowns.</p>	<p>1 I developed a polyamide type column,</p> <p>2 we call it Extreme. It's a column that runs</p> <p>3 things in water, polar solvents, so today our</p> <p>4 polyamides, nylons, proteins, can be run on the</p> <p>5 Extreme material.</p> <p>6 I have a standard line of DVD resins</p> <p>7 that I've developed. Those are selling well.</p> <p>8 And basically there's a whole product</p> <p>9 line. There's SFE product, solid face</p> <p>10 extraction cartridges.</p> <p>11 Q. Is it fair to describe your business</p> <p>12 as a lab that offers analytical chemistry</p> <p>13 services to those who might need it?</p> <p>14 A. Yes.</p> <p>15 Q. And whatever other products you all</p> <p>16 might develop on your own?</p> <p>17 A. The products we developed are no</p> <p>18 like -- I would say we probably have a million</p> <p>19 dollar column inventory here, if we had to go</p> <p>20 out and buy them all, but we save a good portion</p> <p>21 of that money by making them ourselves. And as</p> <p>22 a side bonus, we sell them on the side and make</p> <p>23 money from the sale of them, too, as products.</p> <p>24 That was my business model.</p> <p>25 And when I successfully developed</p>

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<p>1 methods for clients, then they would say -- they</p> <p>2 might say "okay, now you run \$100,000 worth or</p> <p>3 \$200,000 worth of samples, I want to take that</p> <p>4 in-house, sell me the column, turn-key method."</p> <p>5 They've already seen my methods here, they've</p> <p>6 seen the results, they just take the column and</p> <p>7 start running. But now I don't use the total</p> <p>8 business, I have a column customer instead of a</p> <p>9 sample customer.</p> <p>10 Q. So when you talk about the methods,</p> <p>11 you're talking about methods of analytical</p> <p>12 chemistry that you come up with for your</p> <p>13 customers?</p> <p>14 A. Yes.</p> <p>15 Q. Prior to your deposition today, have</p> <p>16 you ever testified or consulted in a medical</p> <p>17 device case?</p> <p>18 A. I have testified. I don't think, I</p> <p>19 don't recall -- well, I have been involved with</p> <p>20 polypropylene implants, artificial hips,</p> <p>21 artificial knees, polyethylene, I believe. I've</p> <p>22 been involved with contact lenses. I don't --</p> <p>23 I've been involved in the legal cases, many</p> <p>24 times they don't go to court, they settle, so</p> <p>25 you say testify, testifying has been less, of</p>	<p>1 A. The same type of thing, molecular</p> <p>2 weight, additives.</p> <p>3 Q. How long ago did you do the hip</p> <p>4 implant work?</p> <p>5 A. The same thing.</p> <p>6 Q. 20 years ago?</p> <p>7 A. 20 years ago-ish.</p> <p>8 Q. Have you done anything in the last ten</p> <p>9 years in hip implants?</p> <p>10 A. No, I haven't seen it recently.</p> <p>11 Q. Do you remember who you worked with on</p> <p>12 hip implants?</p> <p>13 A. No.</p> <p>14 Q. Did you give any depositions in hip</p> <p>15 implant litigation?</p> <p>16 A. I don't think so.</p> <p>17 Q. Do you know whether Jordi Labs works</p> <p>18 on any current hip implant litigation?</p> <p>19 A. No. No, I shouldn't say -- I have to</p> <p>20 say I don't know because I really don't know</p> <p>21 what the current workflow is. I don't talk to</p> <p>22 the customers anymore directly. I used to know</p> <p>23 that intimately, but I don't now.</p> <p>24 Q. Contact lenses, have you done any work</p> <p>25 on contact lenses in the last 15 years?</p>
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<p>1 course, than the work for -- because people will</p> <p>2 come to me and not even tell me it's a legal</p> <p>3 case, then they'll see the results and then tell</p> <p>4 me they want to do more and now they'll tell me</p> <p>5 it's a legal case.</p> <p>6 Q. What did you do in connection with</p> <p>7 knee implants?</p> <p>8 A. I just ran GPC, additives.</p> <p>9 Q. Analytical testing?</p> <p>10 A. Just to see if the polymer was</p> <p>11 degraded over periods of time, if the additives</p> <p>12 were still there, just like we're doing now.</p> <p>13 Q. Did you give any deposition testimony</p> <p>14 in any cases involving knee implants?</p> <p>15 A. It's been 20 years ago. I don't</p> <p>16 recall. I remember running the work, but I</p> <p>17 don't remember what -- how deep into it we got.</p> <p>18 Q. Did you work for the Plaintiff or the</p> <p>19 Defendant?</p> <p>20 A. I worked for the manufacturer,</p> <p>21 whether --</p> <p>22 Q. Do you remember who that was?</p> <p>23 A. No, I don't.</p> <p>24 Q. What about hip implants, what work did</p> <p>25 you do on hip implants?</p>	<p>1 A. I couldn't name the customers. I</p> <p>2 suspect we have because we've worked on</p> <p>3 methacrylate type gels, and hematype gels which</p> <p>4 are used in that kind of product.</p> <p>5 Q. In a litigation context?</p> <p>6 A. No, just analysis.</p> <p>7 Q. For the knees, hips, and contact</p> <p>8 lenses that you just identified, do you recall</p> <p>9 giving any deposition testimony in any of those</p> <p>10 cases?</p> <p>11 A. No.</p> <p>12 Q. Have you ever testified as an expert</p> <p>13 in a medical device case before today?</p> <p>14 A. I don't believe so.</p> <p>15 Q. Have you ever done any work for the</p> <p>16 FDA?</p> <p>17 A. No.</p> <p>18 Q. Ever done any work for Johnson &amp;</p> <p>19 Johnson?</p> <p>20 A. I think we probably have, because</p> <p>21 we've worked for almost all the major</p> <p>22 corporations over the years.</p> <p>23 Q. Do you have a specific recollection of</p> <p>24 working for Johnson &amp; Johnson or any of its</p> <p>25 subsidiaries?</p>

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<p>1 A. I have a recollection, but I couldn't</p> <p>2 even tell you what we did.</p> <p>3 Q. Are you familiar with a company known</p> <p>4 as Ethicon?</p> <p>5 A. Yes.</p> <p>6 Q. Do you have any recollection of ever</p> <p>7 working with Ethicon?</p> <p>8 A. The name sure sounds familiar.</p> <p>9 Q. Do you know the business of Ethicon?</p> <p>10 A. Well, I do, I mean I know one part of</p> <p>11 it at least now, these meshes. I don't know, I</p> <p>12 don't know what else they might be involved in.</p> <p>13 Q. Do you know any business interests</p> <p>14 that Ethicon has beyond the mesh that's involved</p> <p>15 in the litigation about which you're testifying</p> <p>16 today?</p> <p>17 A. Other than the mesh?</p> <p>18 Q. Right.</p> <p>19 A. No.</p> <p>20 Q. And the only reason you know about the</p> <p>21 mesh and its relationship to Ethicon is because</p> <p>22 you're involved in this case, is that fair?</p> <p>23 A. That's right.</p> <p>24 Q. We talked earlier about work that</p> <p>25 Jordi Labs may be doing in litigation involving</p>	<p>1 Q. -- for this work?</p> <p>2 A. What's Greg's last name? I can look</p> <p>3 it up.</p> <p>4 MR. ANDERSON: Elsdon.</p> <p>5 A. Elsdon.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. And what kind of file materials would</p> <p>8 the company typically keep that would govern the</p> <p>9 relationship that it has with a customer, an</p> <p>10 engagement or purchase order or a contract of</p> <p>11 some sort outlining the work you're going to do?</p> <p>12 A. There has to be some kind of</p> <p>13 paperwork, otherwise we wouldn't begin work.</p> <p>14 Q. Anything else?</p> <p>15 A. Not very formal, other than that.</p> <p>16 Q. On the invoices we talked about</p> <p>17 earlier that I marked as an exhibit, there were</p> <p>18 a number of surcharges for rush work. Are you</p> <p>19 familiar with those?</p> <p>20 A. Yes.</p> <p>21 Q. What happened? Why were the</p> <p>22 surcharges made?</p> <p>23 A. Well, like in the Batiste case, the</p> <p>24 sample was explanted recently, and we had to be</p> <p>25 ready for the deposition today, so in order to</p>
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<p>1 Bard. Do you know whether Jordi Labs is doing</p> <p>2 work involving the meshes of any other</p> <p>3 manufacturer?</p> <p>4 A. I don't have any idea.</p> <p>5 Q. Do you have an engagement letter with</p> <p>6 the Plaintiffs in this case?</p> <p>7 A. No.</p> <p>8 Q. Do you know whether Jordi Labs has an</p> <p>9 engagement letter with the Plaintiffs in the</p> <p>10 case?</p> <p>11 A. Well, we have -- we send out</p> <p>12 quotations, and those have to be signed.</p> <p>13 Q. Okay.</p> <p>14 A. Somehow.</p> <p>15 Q. For work that's been done in this</p> <p>16 case, you should have on your file a contract or</p> <p>17 agreement?</p> <p>18 A. That would be -- the way the work is</p> <p>19 handled is it goes through a project manager,</p> <p>20 and the project manager would have that quote.</p> <p>21 He generates the quotes, and then it's approved</p> <p>22 by Mark and others.</p> <p>23 Q. Do you know who the project manager</p> <p>24 is --</p> <p>25 A. Greg.</p>	<p>1 do that it had to be done on a rush basis or it</p> <p>2 wouldn't be ready. Normal turnaround is ten</p> <p>3 days.</p> <p>4 Q. Do you have a pricing policy that</p> <p>5 determines the extent to which you markup work</p> <p>6 for surcharges?</p> <p>7 A. Yeah, they do. It's maybe double. I</p> <p>8 don't -- again, I don't control that. But I'm</p> <p>9 familiar with it.</p> <p>10 Q. For example, on invoice 7881, there's</p> <p>11 a surcharge for rush analytical surfaces of</p> <p>12 \$35,000.</p> <p>13 Would that be a charge in addition to</p> <p>14 what it ordinarily costs?</p> <p>15 A. Yes.</p> <p>16 Q. And again on 7883, 9/11/2013, there's</p> <p>17 another surcharge for \$67,813?</p> <p>18 A. Yes.</p> <p>19 We're basically set up --</p> <p>20 MR. ANDERSON: There's no question.</p> <p>21 THE WITNESS: Sorry.</p> <p>22 MR. ANDERSON: No question pending.</p> <p>23 MR. THOMAS: I'm finished. Thank you.</p> <p>24 MR. ANDERSON: All right. I need to</p> <p>25 take a break, take a few minutes and sit and</p>

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<p>1 talk, and we'll be back on here as soon as we</p> <p>2 can.</p> <p>3 (Whereupon, a recess was taken from</p> <p>4 5:16 p.m. to 5:49 p.m.)</p> <p>5 CROSS EXAMINATION</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. Dr. Jordi, I'm just going to ask you a</p> <p>8 few questions. I know it's been a long day, but</p> <p>9 I just have a few follow-up questions to some of</p> <p>10 the things Mr. Thomas asked you. Okay?</p> <p>11 A. Okay.</p> <p>12 Q. Doctor, all of the testing that we've</p> <p>13 been discussing all day long that was performed</p> <p>14 by Jordi Labs, are all those tests industry</p> <p>15 standard?</p> <p>16 A. Yes. Routine.</p> <p>17 Q. In performing these tests, the ones</p> <p>18 that were done at Jordi Labs, were standard</p> <p>19 operating procedures here at Jordi Labs</p> <p>20 followed?</p> <p>21 A. Yes.</p> <p>22 Q. Were lab notebooks carefully collected</p> <p>23 and each step written down by --</p> <p>24 A. Yes.</p> <p>25 Q. Let me finish.</p>	<p>1 Jordi Labs, and they brought results back to</p> <p>2 you, and you interpreted those results?</p> <p>3 A. That's right.</p> <p>4 Q. Is that also standard in your</p> <p>5 industry?</p> <p>6 A. Absolutely.</p> <p>7 Q. In talking about your opinions</p> <p>8 regarding the degradation of the meshes from</p> <p>9 Ms. Batiste, Ms. Lewis, and the other women</p> <p>10 whose explant samples you reviewed today, do you</p> <p>11 have an opinion as to whether or not those</p> <p>12 meshes would degrade even if there were</p> <p>13 antioxidants present in the polypropylene?</p> <p>14 MR. THOMAS: Object to the form of the</p> <p>15 question.</p> <p>16 A. It's possible that they could if the</p> <p>17 amount of peroxide, superoxide, other oxidants,</p> <p>18 the irritation, the inflammation was great</p> <p>19 enough in a given patient.</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. You said "possible," so we have to</p> <p>22 correct that.</p> <p>23 Do you have an opinion to a reasonable</p> <p>24 degree of medical certainty as to whether or not</p> <p>25 the meshes in Ms. Batiste, Ms. Lewis, and others</p>
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<p>1 -- by Jordi Labs?</p> <p>2 A. Yes.</p> <p>3 Q. And was all of the testing that we've</p> <p>4 described today done at your direction?</p> <p>5 A. Yes, I requested these tests.</p> <p>6 Q. Is it standard or non-standard in your</p> <p>7 industry for someone to assign work or to send</p> <p>8 work of this nature, this type of testing, to</p> <p>9 someone else to perform the testing?</p> <p>10 A. It's standard procedure because</p> <p>11 nobody, almost nobody has enough, except the</p> <p>12 giants, has enough money to have all the</p> <p>13 instruments.</p> <p>14 Q. So when Mr. Thomas was questioning you</p> <p>15 about some of the jobs you sent to Evans, and</p> <p>16 you said sometimes Evans sends jobs to you, is</p> <p>17 that standard in your industry?</p> <p>18 A. Absolutely.</p> <p>19 Q. Therefore, was it standard for you to</p> <p>20 send some of the FTIR microscopy and other tests</p> <p>21 out to Evans to have them send you the results?</p> <p>22 A. Yes.</p> <p>23 Q. In preparing your report in this case</p> <p>24 and providing your opinions, is it fair to say</p> <p>25 that you assigned these projects to folks at</p>	<p>1 could still degrade showing the cracking on SEM</p> <p>2 and showing SEM-EDX analysis of the particles to</p> <p>3 be polypropylene even if there was antioxidants</p> <p>4 present in the mesh?</p> <p>5 MR. THOMAS: Object to the form of the</p> <p>6 question.</p> <p>7 MR. ESTEE: Object to form.</p> <p>8 A. It's certainly -- the antioxidants can</p> <p>9 be overcome if you throw enough oxidant at the</p> <p>10 polymer.</p> <p>11 BY MR. ANDERSON:</p> <p>12 Q. Is the sole basis for stating that</p> <p>13 antioxidants can leach from polypropylene just</p> <p>14 your work done in this case, or are there other</p> <p>15 bases for that opinion?</p> <p>16 MR. THOMAS: Object to the form of the</p> <p>17 question.</p> <p>18 A. Certainly additives bloom at varying</p> <p>19 rates depending on their compatibility with the</p> <p>20 polymer system they're put in. So Santonox R</p> <p>21 can bloom, most any additive can bloom at some</p> <p>22 rate, and the less compatible it is with the</p> <p>23 polymer the faster it will bloom, and hence the</p> <p>24 faster it will be lost. So polymers can lose</p> <p>25 their antioxidants even if they're stabilized</p>

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<p>1 initially. In fact, they all do at some rate.</p> <p>2 BY MR. ANDERSON:</p> <p>3 Q. And is that knowledge that you just</p> <p>4 expressed based only upon the studies that you</p> <p>5 did here, or is that something that you brought</p> <p>6 with you before this litigation?</p> <p>7 MR. THOMAS: Object to the form of the</p> <p>8 question.</p> <p>9 A. No, the -- over 30 years of experience</p> <p>10 and articles I've read, books I've read, other</p> <p>11 samples I've analyzed, it can be -- they can</p> <p>12 lose their antioxidants, as well as we showed it</p> <p>13 in the study. But that certainly isn't the only</p> <p>14 reason I believe they're lost.</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. Right at the end of some of the</p> <p>17 questioning there was some -- Mr. Thomas asked</p> <p>18 you some questions about some rush charges on</p> <p>19 the bills.</p> <p>20 Do you remember those? Do you</p> <p>21 remember those questions?</p> <p>22 A. Yes, sir.</p> <p>23 Q. Is it standard in your industry if</p> <p>24 someone asks you to do a quick turnaround on</p> <p>25 testing that you charge a rush charge?</p>	<p>1 questioning?</p> <p>2 A. Mm-hmm.</p> <p>3 Q. Yes?</p> <p>4 A. Yes.</p> <p>5 Q. There was some question by Mr. Thomas</p> <p>6 as to whether or not you should have used sodium</p> <p>7 hypochlorite in order to clean the materials.</p> <p>8 Do you remember that part of the</p> <p>9 questioning?</p> <p>10 A. Yes.</p> <p>11 MR. THOMAS: Object to the form of the</p> <p>12 question.</p> <p>13 MR. ANDERSON: I'm trying to redirect</p> <p>14 the witness back to that area of the</p> <p>15 questioning.</p> <p>16 BY MR. ANDERSON:</p> <p>17 Q. By not applying sodium hypochlorite to</p> <p>18 the fibers in order to remove some of the</p> <p>19 proteins, would that change any of your opinions</p> <p>20 with regard to whether or not the meshes in</p> <p>21 Ms. Lewis, Ms. Batiste, and the other women</p> <p>22 whose explanted meshes you looked at degraded on</p> <p>23 SEM analysis?</p> <p>24 A. No. The fact is that you could</p> <p>25 clearly see the degradation, it had no bearing</p>
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<p>1 A. Absolutely is.</p> <p>2 Q. So that wasn't something just special</p> <p>3 to me, that's something your company does all</p> <p>4 the time?</p> <p>5 A. We -- yes. Absolutely.</p> <p>6 Q. Do other companies in your industry do</p> <p>7 the same thing?</p> <p>8 A. Absolutely.</p> <p>9 Q. Does your dry cleaners do it, too?</p> <p>10 Withdraw the question.</p> <p>11 And why is it that your company would</p> <p>12 charge a rush fee?</p> <p>13 A. We have to turn away other work, we</p> <p>14 have to put other projects on hold, potentially</p> <p>15 if we get enough of this type of thing, angering</p> <p>16 some clients. So it's a difficult management</p> <p>17 decision on how to handle it.</p> <p>18 Q. Does it put an increase on your</p> <p>19 workload for your employees?</p> <p>20 A. Absolutely.</p> <p>21 Q. Let me take you back to a part of your</p> <p>22 testimony regarding cleaning the material or,</p> <p>23 let's call it, preparing the fibers prior to</p> <p>24 certain testing being done at Jordi Labs.</p> <p>25 Do you remember that part of your</p>	<p>1 whatsoever.</p> <p>2 Q. What change, if any, would applying</p> <p>3 sodium hypochlorite have to any of the test</p> <p>4 results that you obtained for Ms. Lewis,</p> <p>5 Ms. Batiste, and the other women?</p> <p>6 A. It would have removed the protein from</p> <p>7 the surface of the mesh so that the infrared</p> <p>8 spectrum would -- the protein bands in the</p> <p>9 infrared spectrum would have gone away.</p> <p>10 Q. Whether or not those bands are present</p> <p>11 or not present, can you still see other evidence</p> <p>12 of oxidation on those bands?</p> <p>13 A. We still saw the 1760 band and the</p> <p>14 1740 shoulder in spite of that. So they're both</p> <p>15 still there, both of which indicate oxidation.</p> <p>16 Q. You were shown by Mr. Thomas Jordi</p> <p>17 Exhibit 3, that was this Renaud de Tayrac and</p> <p>18 Letouzey article.</p> <p>19 Do you recall that?</p> <p>20 A. Yes, I do.</p> <p>21 Q. Were the meshes that were --</p> <p>22 A. I got it.</p> <p>23 Q. Were the meshes that were explanted</p> <p>24 and analyzed in that study coming from women?</p> <p>25 A. No, it says in Figure 1 they were</p>

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<p>1 coming from Wistar rats.</p> <p>2 Q. From rats, is that what you said?</p> <p>3 A. Yes. Wistar rats.</p> <p>4 Q. And when animal studies are used in a</p> <p>5 preclinical model, do they typically use healthy</p> <p>6 rats?</p> <p>7 A. Yes.</p> <p>8 Q. Was the explanted tissue coming from</p> <p>9 these women coming from healthy tissue?</p> <p>10 MR. THOMAS: Object to the form of the</p> <p>11 question.</p> <p>12 A. From here, from this figure?</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. From the women whose explanted meshes</p> <p>15 you looked at. I'll withdraw -- that's okay,</p> <p>16 I'll withdraw the question.</p> <p>17 He used D -- well, these authors used</p> <p>18 DMSO as well as ultrasonic treatment in order to</p> <p>19 remove what they claim to be just the proteins</p> <p>20 from the fibers.</p> <p>21 Do you recall that?</p> <p>22 A. I do.</p> <p>23 Q. Do you believe that's a scientifically</p> <p>24 valid method in which to determine what is</p> <p>25 flaking off of the meshes?</p>	<p>1 There's no proof there by any chemical testing.</p> <p>2 Q. Do you recall during part of your --</p> <p>3 during part of the questioning by Mr. Thomas, he</p> <p>4 was asking you whether or not you or someone at</p> <p>5 Jordi Labs performed any analysis on hydrogen</p> <p>6 peroxide or any other products of inflammation</p> <p>7 that may have occurred in the women's tissue</p> <p>8 before these meshes were explanted? Do you</p> <p>9 remember that part of your testimony?</p> <p>10 A. I do.</p> <p>11 Q. Are you aware of any test out there</p> <p>12 that would allow you to look at the products of</p> <p>13 inflammation in and around mesh fibers that have</p> <p>14 been explanted and put into formalin and shipped</p> <p>15 to you for analysis?</p> <p>16 A. Absolutely not, because it's been</p> <p>17 washed away.</p> <p>18 Q. Would it matter to your opinions</p> <p>19 regarding the degradation of these meshes in</p> <p>20 this case whether or not hydrogen peroxide was</p> <p>21 present in the body at that time?</p> <p>22 A. No, it would not, because the damage</p> <p>23 was observed in SEM and other techniques, like</p> <p>24 IR.</p> <p>25 Q. Do you, to a reasonable degree of</p>
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<p>1 A. I do not.</p> <p>2 Q. And why is that?</p> <p>3 A. If you use sonication you're using a</p> <p>4 battering ram to knock the cracked material off,</p> <p>5 and so if you knock the material off you're</p> <p>6 removing the very thing that you want to look</p> <p>7 at. They did not -- now, if they had run</p> <p>8 infrared or some other technique to look at the</p> <p>9 structure of the material coming off chemically,</p> <p>10 it would have been helpful, but none of that was</p> <p>11 done. So it was just blasted clean, and say it</p> <p>12 never was polypropylene, but we know it was</p> <p>13 polypropylene because we looked at it in our</p> <p>14 particles, and we saw that it was polypropylene.</p> <p>15 Of course it did have some protein in it, but it</p> <p>16 was mostly polypropylene.</p> <p>17 Q. So do you find this article to be</p> <p>18 scientifically reliable with regard to whether</p> <p>19 or not TVT mesh degrades in women? Do you find</p> <p>20 this article to be scientifically valid with</p> <p>21 regard to whether or not the TVT meshes degrade</p> <p>22 in women?</p> <p>23 A. I do not. I think -- I'm surprised it</p> <p>24 was published without some requirement to do</p> <p>25 structural analysis to prove their claim.</p>	<p>1 medical -- to a reasonable degree of medical</p> <p>2 certainty --</p> <p>3 MR. THOMAS: Scientific certainty.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. What did I say? Medical? It's been a</p> <p>6 long day.</p> <p>7 Doctor, do you have an opinion to a</p> <p>8 reasonable degree of scientific certainty as to</p> <p>9 whether or not you need to know whether hydrogen</p> <p>10 peroxide, superoxides, or any other mediators or</p> <p>11 inflammatory products that would have been</p> <p>12 produced in the body were present on the meshes</p> <p>13 by the time you analyzed them in order to</p> <p>14 determine whether or not these meshes degraded?</p> <p>15 A. I don't see why we'd need to determine</p> <p>16 that.</p> <p>17 Q. And why is that?</p> <p>18 A. It wouldn't matter. We see the</p> <p>19 degradation, the oxidation has already occurred,</p> <p>20 we don't need to say hydrogen peroxide or</p> <p>21 hydroxide radicals at this point, we need to see</p> <p>22 the chemical damage that's been done to the</p> <p>23 material. It either has or has not occurred.</p> <p>24 Q. Do you recall some questioning by</p> <p>25 Mr. Thomas where you were looking at the FTIR</p>

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<p>1 microscopy, and there was a picture of one of</p> <p>2 the shards of polypropylene that had come off</p> <p>3 one of the meshes?</p> <p>4 A. Yes.</p> <p>5 Q. Do you recall that? Don't cut me off</p> <p>6 if you can.</p> <p>7 Do you recall that?</p> <p>8 A. Yes.</p> <p>9 Q. Do you recall that he asked you how</p> <p>10 many of these particles came off of the fibers?</p> <p>11 Do you remember that?</p> <p>12 A. Yes.</p> <p>13 Q. Did you feel the need to count each</p> <p>14 and every particle that came off of those fibers</p> <p>15 in order to allow you to make an opinion as to</p> <p>16 whether or not those FTIR microscopy analyses</p> <p>17 showed that the shards contained polypropylene?</p> <p>18 A. I saw no need, because you can look at</p> <p>19 the cracked region, and if it came off in bits</p> <p>20 and pieces, each piece would be the same. It</p> <p>21 all looks identical.</p> <p>22 Q. And just give us an estimate of how</p> <p>23 many of these particles were falling off just</p> <p>24 one of these small pieces of fibers; are we</p> <p>25 talking tens, twenties, dozens?</p>	<p>1 Q. How much oxidation was required for</p> <p>2 Ms. Lewis, Ms. Batiste, and these other 21</p> <p>3 women?</p> <p>4 A. Enough to cause the flaking that was</p> <p>5 observed.</p> <p>6 MR. THOMAS: Object to form of the</p> <p>7 question. Move to strike.</p> <p>8 MR. ESTEE: Object to form.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. How much oxidation was required for</p> <p>11 the mesh samples for Linda Batiste, Carolyn</p> <p>12 Lewis, and all the other women whose meshes you</p> <p>13 observed in order to flake?</p> <p>14 MR. THOMAS: Object to the form of the</p> <p>15 question.</p> <p>16 MR. ESTEE: Form.</p> <p>17 A. That's an impossible question for me</p> <p>18 to answer. I know that there was enough because</p> <p>19 it did flake and it was observed in the SEM.</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. If polypropylene fibers flake in the</p> <p>22 manner in which those that you observed in this</p> <p>23 testing flaked and peeled off, would that allow</p> <p>24 this mesh to function for its intended purpose?</p> <p>25 MR. THOMAS: Object to form of the</p>
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<p>1 A. I have no idea.</p> <p>2 Q. It's that many?</p> <p>3 MR. THOMAS: Object to form.</p> <p>4 A. In some cases, like this case, this</p> <p>5 article --</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. No, we're going to focus on in this</p> <p>8 case.</p> <p>9 A. Okay.</p> <p>10 Q. The amount of material. Let's focus</p> <p>11 on that.</p> <p>12 In the photographs that were done by</p> <p>13 Evans on the FTIR microscopy when they showed</p> <p>14 the various pieces, did you need to test 10, 20,</p> <p>15 30 of those pieces to confirm the results that</p> <p>16 you had on your FTIR microscopy?</p> <p>17 MR. THOMAS: Object to the form of the</p> <p>18 question.</p> <p>19 A. No. I mean they're all the same.</p> <p>20 BY MR. ANDERSON:</p> <p>21 Q. Do you recall being asked a question</p> <p>22 as to how much oxidation is required to cause</p> <p>23 the polypropylene fibers to begin to flake? Do</p> <p>24 you recall that part of your questioning?</p> <p>25 A. Yes.</p>	<p>1 question.</p> <p>2 MR. ESTEE: Object to form.</p> <p>3 A. I would think it would cause</p> <p>4 irritation in the body, so I would think not.</p> <p>5 That is a question primarily for the medical</p> <p>6 doctors to answer as far as the damage it might</p> <p>7 or might not do. But it certainly can't be good</p> <p>8 to be putting knife edges in tissue.</p> <p>9 BY MR. ANDERSON:</p> <p>10 Q. Is it your understanding that these</p> <p>11 are supposed to be permanently implanted in a</p> <p>12 woman's pelvic tissues?</p> <p>13 A. Yes.</p> <p>14 Q. Given the amount of degradation that</p> <p>15 you've seen in your testing, do you believe that</p> <p>16 it would perform its intended purpose of being</p> <p>17 permanently implanted in these women's bodies</p> <p>18 without causing some problems with the polymer</p> <p>19 structures?</p> <p>20 MR. THOMAS: Object to the form of the</p> <p>21 question.</p> <p>22 A. Absolutely not.</p> <p>23 BY MR. ANDERSON:</p> <p>24 Q. Explain what you mean by that.</p> <p>25 A. Well, these shards come off, they're</p>

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<p>1 going to cause inflammation, and it's going to</p> <p>2 be a problem.</p> <p>3 MR. THOMAS: Move to strike.</p> <p>4 BY MR. ANDERSON:</p> <p>5 Q. Had these meshes continued to be in</p> <p>6 these women's bodies, would you -- strike that.</p> <p>7 Is degradation of polymer, like you've</p> <p>8 seen in this testing, progressive?</p> <p>9 MR. THOMAS: Object to form of the</p> <p>10 question.</p> <p>11 A. Yes. It definitely is. It starts on</p> <p>12 the surface and apparently works its way in, as</p> <p>13 we've seen by SEM-EDX presence of oxygen in the</p> <p>14 second underlying layer.</p> <p>15 BY MR. ANDERSON:</p> <p>16 Q. So do you have an opinion to a</p> <p>17 reasonable degree of scientific certainty as to</p> <p>18 whether or not the longer these mesh fibers are</p> <p>19 in the body the more degradation will occur? Do</p> <p>20 you have an opinion on that?</p> <p>21 A. I think the data shows that it's going</p> <p>22 to degrade like the layers of an onion, layer</p> <p>23 after layer.</p> <p>24 Q. You were asked some questions about --</p> <p>25 from Mr. Thomas as to whether or not you used a</p>	<p>1 to whether or not you found anything in the</p> <p>2 FTIR, evidence of oxidation at band 1730 to</p> <p>3 1680.</p> <p>4 Do you recall that?</p> <p>5 A. Yes.</p> <p>6 Q. Does it matter to you whether or not</p> <p>7 you can find evidence of oxidation in the FTIR</p> <p>8 at 1730 to 1680 in order to hold the opinion</p> <p>9 that this mesh degraded in this woman's body?</p> <p>10 A. Not really, because the fact is it did</p> <p>11 degrade and we saw it in the SEM. That's just</p> <p>12 simply a fact.</p> <p>13 Q. Is all of the testing that was done</p> <p>14 for Carolyn Lewis and Linda Batiste contained in</p> <p>15 the reports that you've provided?</p> <p>16 A. Was all of the testing?</p> <p>17 Q. Is all of the testing that was done at</p> <p>18 your direction provided in the reports that</p> <p>19 you've given today for both Linda Batiste and</p> <p>20 Carolyn Lewis?</p> <p>21 A. Well, with the possible exception of</p> <p>22 the --</p> <p>23 Q. Let me see if I can withdraw that.</p> <p>24 Is all the testing that forms the</p> <p>25 basis of your opinions that the mesh degraded in</p>
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<p>1 standard over here for polypropylene, for FTIR,</p> <p>2 or a standard over here. Do you remember that</p> <p>3 part of your questioning?</p> <p>4 A. Right.</p> <p>5 Q. Do you need an FTIR for polypropylene</p> <p>6 -- sorry. Strike that.</p> <p>7 Do you need an FTIR standard for</p> <p>8 polypropylene in order to determine whether or</p> <p>9 not the polypropylene in these meshes oxidized</p> <p>10 and degraded?</p> <p>11 A. Absolutely not.</p> <p>12 Q. Please explain that.</p> <p>13 A. Because we have -- the carbonyl is</p> <p>14 going to show up at 1740, 1730, 17 whatever, 15,</p> <p>15 or 1700 depending on the form, or a mix of all</p> <p>16 of those, and that's going to be there in a</p> <p>17 polypropylene. So if the carbonyl shows up,</p> <p>18 it's going to be separate from the bands of the</p> <p>19 polypropylene. Polypropylene doesn't have any</p> <p>20 bands there.</p> <p>21 Q. Do you recall, if you could just turn</p> <p>22 to Pages 67 and 69 of your report, you were</p> <p>23 looking at some FTIR micro with Mr. Thomas?</p> <p>24 A. Yes.</p> <p>25 Q. And you were asked some questions as</p>	<p>1 Linda Batiste and Carolyn Lewis available in the</p> <p>2 reports that you've provided today?</p> <p>3 A. Yes.</p> <p>4 MR. THOMAS: Object to the form of the</p> <p>5 question.</p> <p>6 BY MR. ANDERSON:</p> <p>7 Q. In other words, if you wanted to speak</p> <p>8 to the results for all of the testing that was</p> <p>9 done showing degradation as you've described</p> <p>10 previously here for the jury for Carolyn Lewis</p> <p>11 and Linda Batiste, you'd be able to point us to</p> <p>12 each one of those testing as Mr. Thomas went</p> <p>13 through with you today, correct?</p> <p>14 MR. THOMAS: Object to form.</p> <p>15 MR. ESTEE: Form.</p> <p>16 MR. ANDERSON: Form.</p> <p>17 A. That's correct.</p> <p>18 BY MR. ANDERSON:</p> <p>19 Q. Based on your knowledge, training,</p> <p>20 background, experience, your work history with</p> <p>21 polymers as you described it here today, your</p> <p>22 work as a biochemist and a polymer chemist, and</p> <p>23 all of the materials that you reviewed in this</p> <p>24 case, including the testing that was done at</p> <p>25 your direction, do you have an opinion to a</p>

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<p>1 reasonable degree of scientific certainty as to</p> <p>2 whether or not the polypropylene mesh, Prolene</p> <p>3 mesh TVT implanted in Carolyn Lewis, degraded</p> <p>4 while in her body?</p> <p>5 MR. THOMAS: Object to the form of the</p> <p>6 question.</p> <p>7 MR. ESTEE: Object to form.</p> <p>8 BY MR. ANDERSON:</p> <p>9 Q. Do you have an opinion?</p> <p>10 A. I absolutely do.</p> <p>11 Q. What is that opinion?</p> <p>12 MR. THOMAS: Objection to form.</p> <p>13 MR. ESTEE: Form.</p> <p>14 A. It's obvious, you can see the</p> <p>15 cracking.</p> <p>16 BY MR. ANDERSON:</p> <p>17 Q. And do you have an opinion to a</p> <p>18 reasonable degree of scientific certainty based</p> <p>19 upon your knowledge, training, background,</p> <p>20 education, all of your work history for greater</p> <p>21 than 30 years, 40 years, your work here at Jordi</p> <p>22 Labs, as well as all of the materials that</p> <p>23 you've reviewed in this case, including the</p> <p>24 testing that was done for the explant sample for</p> <p>25 Linda Batiste, as to whether or not the mesh in</p>	<p>1 MR. ESTEE: No. We will reserve any</p> <p>2 questions until the time of trial.</p> <p>3 MR. THOMAS: Thank you.</p> <p>4 (Whereupon, the deposition was</p> <p>5 concluded at 6:11 p.m.)</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
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<p>1 Linda Batiste degraded in her body?</p> <p>2 MR. THOMAS: Objection.</p> <p>3 MR. ESTEE: Form.</p> <p>4 A. It did degrade. I saw the damage.</p> <p>5 BY MR. ANDERSON:</p> <p>6 Q. And what is the basis for that, the</p> <p>7 damage that you saw, the testing that you saw?</p> <p>8 MR. THOMAS: Objection.</p> <p>9 A. We saw increased carbonyls in the</p> <p>10 infrared. We saw the increased oxygen in</p> <p>11 SEM-EDX. We saw the lack of antioxidants, which</p> <p>12 would predispose the polymer to oxidation.</p> <p>13 BY MR. ANDERSON:</p> <p>14 Q. Did the SEM photos also support your</p> <p>15 opinions in that regard?</p> <p>16 A. They were the -- they were proof</p> <p>17 positive really. That just shows it's fact, it</p> <p>18 happened. We can argue about how it happened,</p> <p>19 but it's definitely a fact that it did happen.</p> <p>20 MR. ANDERSON: I don't have anything</p> <p>21 further.</p> <p>22 MR. THOMAS: Anybody on the phone?</p> <p>23 MR. ESTEE: I'm sorry?</p> <p>24 MR. THOMAS: Do you have any</p> <p>25 questions?</p>	<p>1 COMMONWEALTH OF MASSACHUSETTS )</p> <p>2 SUFFOLK, SS. )</p> <p>3 I, MAUREEN O'CONNOR POLLARD, RPR, CLR,</p> <p>4 and Notary Public in and for the Commonwealth of</p> <p>5 Massachusetts, do certify that on the 30th day</p> <p>6 of October, 2013, at 9:05 o'clock, the person</p> <p>7 above-named was duly sworn to testify to the</p> <p>8 truth of their knowledge, and examined, and such</p> <p>9 examination reduced to typewriting under my</p> <p>10 direction, and is a true record of the testimony</p> <p>11 given by the witness. I further certify that I</p> <p>12 am neither attorney, related or employed by any</p> <p>13 of the parties to this action, and that I am not</p> <p>14 a relative or employee of any attorney employed</p> <p>15 by the parties hereto, or financially interested</p> <p>16 in the action.</p> <p>17 In witness whereof, I have hereunto</p> <p>18 set my hand this 1st day of November, 2013.</p> <p>19</p> <p>20</p> <p>21 _____</p> <p>22 MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC</p> <p>23 Realtime Systems Administrator</p> <p>24 CSR #149108</p> <p>25</p>

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<p style="text-align: right;">Page 310</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it. It will be</p> <p>10 attached to your deposition.</p> <p>11 It is imperative that you</p> <p>12 return the original errata sheet to the</p> <p>13 deposing attorney within thirty (30) days</p> <p>14 of receipt of the deposition transcript</p> <p>15 by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 312</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, and that the same</p> <p>6 is a correct transcription of the answers</p> <p>7 given by me to the questions therein</p> <p>8 propounded, except for the corrections or</p> <p>9 changes in form or substance, if any,</p> <p>10 noted in the attached Errata Sheet.</p> <p>11</p> <p>12 _____</p> <p>13 HOWARD C. JORDI, PH.D. DATE</p> <p>14</p> <p>15 Subscribed and sworn</p> <p>16 to before me this</p> <p>17 _____ day of _____, 20____.</p> <p>18 My commission expires: _____</p> <p>19 _____</p> <p>20 Notary Public</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 311</p> <p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 REASON: _____</p> <p>6 _____</p> <p>7 REASON: _____</p> <p>8 _____</p> <p>9 REASON: _____</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 _____</p> <p>13 REASON: _____</p> <p>14 _____</p> <p>15 REASON: _____</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 _____</p> <p>19 REASON: _____</p> <p>20 _____</p> <p>21 REASON: _____</p> <p>22 _____</p> <p>23 REASON: _____</p> <p>24 _____</p> <p>25 REASON: _____</p>	<p style="text-align: right;">Page 313</p> <p>1 LAWYER'S NOTES</p> <p>2 PAGE LINE</p> <p>3 _____</p> <p>4 _____</p> <p>5 _____</p> <p>6 _____</p> <p>7 _____</p> <p>8 _____</p> <p>9 _____</p> <p>10 _____</p> <p>11 _____</p> <p>12 _____</p> <p>13 _____</p> <p>14 _____</p> <p>15 _____</p> <p>16 _____</p> <p>17 _____</p> <p>18 _____</p> <p>19 _____</p> <p>20 _____</p> <p>21 _____</p> <p>22 _____</p> <p>23 _____</p> <p>24 _____</p> <p>25 _____</p>

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